

US3272078 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:24:48

All time stamps listed in this document are displayed in GMT

US3272078

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Participant ID

US3272078

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

US3272078

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 14:53:00

Generated On: 09 Jun 2021 16:24:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3272078

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Apr 2021 14:53:00

Generated On: 09 Jun 2021 16:24:48

Date of Birth (MMM yyyy)	(b) (6)	1981
Age		39
Age Units		YEARS
Age (Derived)		39
Sex	Female	<input checked="" type="radio"/>
	Male	<input type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input checked="" type="radio"/>
	Not Reported	<input type="radio"/>
	Unknown	<input type="radio"/>
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

US3272078

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Apr 2021 14:53:00

Generated On: 09 Jun 2021 16:24:48

Date of Informed Consent (*dd MMM yyyy*) 07 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3272078

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 14:53:00

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3272078

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Apr 2021 14:53:00

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Were any significant conditions reported?

Yes ☒
No ☐

US3272078

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3272078

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

Condition	PERIMENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3272078

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

Condition	BACK ACHE
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3272078

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 14:53:00

Generated On: 09 Jun 2021 16:24:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:50
Height (xxx.x)	170 cm
Weight (xxx.x)	74.3 kg
BMI (xxx.x)	25.70934 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272078

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 14:53:00

Generated On: 09 Jun 2021 16:24:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 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

Data signed: (b) (4) 09 Apr 2021 14:53:00

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Date of assessment (dd MMM yyyy) 07 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

Data signed: (b) (4) 09 Apr 2021 14:53:00

Generated On: 09 Jun 2021 16:24:48

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 07 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

Data signed: (b) (4) 09 Apr 2021 14:53:00

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 14:53:00

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

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 101848

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:50
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:52
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

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) _____

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 07 AUG 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 11:22

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

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	07 AUG 2020
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Collection time (00:00-23:59)	10:20 (24 HR)
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Collection date and time (derived)	07 AUG 2020 10:20
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US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:00	07 AUG 2020 10:00
Nasopharyngeal Swab 2	No		

US3272078

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

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 07 AUG 2020 11:48

PC Open Date & Time 07 AUG 2020 11:42

PC Close Date & Time 07 AUG 2020 14:12

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	07 AUG 2020 15:47
PC Open Date & Time	07 AUG 2020 15:07
PC Close Date & Time	08 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:06

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 12:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 12:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

11 AUG 2020 14:17

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

12 AUG 2020 12:00

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 13:05

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 11:46

PC Open Date & Time

07 AUG 2020 11:42

PC Close Date & Time

07 AUG 2020 14:12

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 15:48

PC Open Date & Time

07 AUG 2020 15:07

PC Close Date & Time

08 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 12:06

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 12:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 14:17

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:00

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 13:05

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 11:47
PC Open Date & Time	07 AUG 2020 11:42
PC Close Date & Time	07 AUG 2020 14:12

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 15:48
PC Open Date & Time	07 AUG 2020 15:07
PC Close Date & Time	08 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:06
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:24
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 12:00
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 14:18
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 1811

EAB) (1725)

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:00
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 13:06
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3272078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	08:59 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 08:59
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	10:43 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:43
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3272078

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	04 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 04 SEP 2020

What was the treatment time? (00:00-23:59) 09:55 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 09:55

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

US3272078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	04 SEP 2020
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Collection time (00:00-23:59)	09:12 (24 HR)
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Collection date and time (derived)	04 SEP 2020 09:12
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US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:04	04 SEP 2020 09:04
Nasopharyngeal Swab 2	No		

US3272078

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

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

04 SEP 2020 10:43

PC Open Date & Time

04 SEP 2020 10:15

PC Close Date & Time

04 SEP 2020 12:45

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

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

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

PC Time Stamp 05 SEP 2020 09:45

PC Open Date & Time 04 SEP 2020 13:40

PC Close Date & Time 05 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 15:18

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

08 SEP 2020 12:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

10 SEP 2020 17:45

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 10:46

PC Open Date & Time

04 SEP 2020 10:15

PC Close Date & Time

04 SEP 2020 12:45

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 09:45

PC Open Date & Time

04 SEP 2020 13:40

PC Close Date & Time

05 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 22:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

18

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

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

Yes ☒

No ☐

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

14

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 12:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

8

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

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

Yes ☒

No ☐

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

8

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 15:19

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

8

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 17:45

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 10:46
PC Open Date & Time	04 SEP 2020 10:15
PC Close Date & Time	04 SEP 2020 12:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 09:46
PC Open Date & Time	04 SEP 2020 13:40
PC Close Date & Time	05 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:19
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 15:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:06
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:46
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3272078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:12:56

Generated On: 09 Jun 2021 16:24:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	01 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:13:18

Generated On: 09 Jun 2021 16:24:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 10:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272078

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:12:56

Generated On: 09 Jun 2021 16:24:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3272078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:12:56

Generated On: 09 Jun 2021 16:24:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	10:58 (24 HR)
Collection date and time (derived)	01 OCT 2020 10:58

US3272078

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:56

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 OCT 2020 13:00:25

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 11:04:38

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 15:36:49

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 10:54:01

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

13 NOV 2020 12:01:06

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 NOV 2020 15:57:28
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 12:05:09
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 00:02:29
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 14:03:09

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 13:16:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:10:18

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 11:45:20
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 08:17:07

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 12:00:19
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 12:51:06
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 21:29:43

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 14:35:22

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 12:02:24

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 16:11:33

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 12:32:17

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 00:48:50

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 MAR 2021 13:56:56
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 APR 2021 10:13:08
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 17:59:18

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 09:32:02

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 17:18:29

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3272078

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:24:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	28 FEB 2021 02:36:37

US3272078

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:13:18

Generated On: 09 Jun 2021 16:24:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:13:18

Generated On: 09 Jun 2021 16:24:48

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 _____

Height (derived) _____

Weight (derived) _____

US3272078

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:13:18

Generated On: 09 Jun 2021 16:24:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3272078

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:13:18

Generated On: 09 Jun 2021 16:24:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	15 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	15 MAR 2021 10:30
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US3272078

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:13:18

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272078

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272078

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272078

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:24:48

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3272078

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:24:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	15 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:43 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	15 JAN 2021 13:43
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US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	13:46
Collection Date and Time (derived)	15 JAN 2021 13:46

US3272078

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

AEID	USA-US070-2021-MRNA-1273-P30 1000008
Adverse event	POSTOPERATIVE HEMATOMA OF BREAST, LEFT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	28 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

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

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

SUBJECT HAD OUTPATIENT
BREAST REDUCTION
25MAR2021. DEVELOPED
POSTOPERATIVE HEMATOMA
OF LEFT BREAST, BLOOD LOSS
700-800 CC. FOLLOW UP
SURGICAL EVACUATION AND
INPATIENT ADMISSION. 2
UNITS PRBC TRANSFUSED
25MAR2021 AND 2 UNITS PRBC
27MAR2021. DISMISSED
27MAR2021. DOES NOT RECALL
MEDICATIONS GIVEN.
REQUEST FOR RECORDS SENT
TO HOSPITAL AND TWO
CLINICS FOR FOLLOW-UP
VISITS. AWAITING RESPONSE.

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

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

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

Yes ☒

No ☐

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

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

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

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Name of Medication BIOIDENTICAL HORMONE
(TESTOSTERONE)

Prophylaxis Yes ☐
No ☒

Indication PREMENOPAUSAL

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

EVERY 3 DAYS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC INJECTION

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify EVERY 3 MONTH

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication REDUCTION MAMMOPLASTY

Dose per administration NONE

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify NOT SPECIFIED

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

Name of Medication ULTRAM

Prophylaxis Yes ☐
No ☒

Indication REDUCTION MAMMOPLASTY

Dose per administration NOT SPECIFIED

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify NOT SPECIFIED

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:59:19

Generated On: 09 Jun 2021 16:24:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 14 Apr 2021 19:01:59

Generated On: 09 Jun 2021 16:24:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 MAR 2021	REDUCTION MAMMOPLASTY	Medical History	
25 MAR 2021	EVACUATION OF HEMATOMA, LEFT BREAST	Adverse Event	
25 MAR 2021	LIPOSUCTION	Other	COSMETIC

US3272078

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:24:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3272078

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:24:48

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

SAEID	USA-US070-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 17:12:55

Generated On: 09 Jun 2021 16:24:48

SAEID	USA-US070-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	12/APR/2021 17:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3272078 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272078

Form: Participant Creation

Generated On: 09 Jun 2021 16:24:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:10:07
User entered 'US3272078'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:07

US3272078

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:03:45
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:32

US3272078

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:44:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:27:29
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	16 Nov 2020 20:26:28
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	16 Nov 2020 20:22:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 20:22:57
User entered '05 Aug 2020' reason for change: Data Entry Error		16 Nov 2020 20:22:57
DataPoint Verified.		10 Sep 2020 17:03:45
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:08

US3272078

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:03:45
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:32

US3272078

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'SCRN'	System	07 Aug 2020 16:40:32

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered (b) (6)1981'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:09

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '39'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'YEARS'	System	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '39'	System	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered 'Female (F)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered 'I'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered empty.	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:48

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:34
User entered '0'	Ashley Bell (b) (4)	07 Aug 2020 16:40:26

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:45:31
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:27:37
DataPoint Un-verified.		16 Nov 2020 20:26:28
User entered '05 Aug 2020' reason for change: Data Entry Error		16 Nov 2020 20:26:28
DataPoint Verified.		10 Sep 2020 17:04:41
User entered '07 Aug 2020'	Ashley Bell (b) (4)	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'Aug 2020'	System	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '2020'	System	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:41
User entered 'Amendment 1 (1)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:41
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:41
User entered empty.	Ashley Bell (b) (4)	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:41
User entered empty.	Ashley Bell (b) (4)	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:41
User entered 'No (N)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:07

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:08

US3272078

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '1'	System	07 Aug 2020 16:40:37

US3272078

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:46
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Aug 2020 16:40:37

US3272078

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:24:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:51
User entered 'Yes (Y)'		28 Aug 2020 20:59:06

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:00:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:00:47
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 20:59:38
User entered 'anxiety'	(b) (4), (b) (6)	28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered 'UN UNK 2017'		28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered '0'		28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered 'Yes (Y)'		28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered empty.		28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered '0'		28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'Jan 2017'	System	28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '2017'	System	28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	28 Aug 2020 20:59:36

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Perimenopause - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:01:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:01:47
Data point term sent to Coder	System	28 Aug 2020 21:00:39
User entered 'perimenopause'	(b) (4), (b) (6)	28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered 'UN UNK 2018'		28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered '0'		28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered 'Yes (Y)'		28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered empty.		28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:04:58
User entered '0'		28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'Jan 2018'	System	28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '2018'	System	28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	28 Aug 2020 20:59:58

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:29
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back ache - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 16:27:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 16:27:53
Data point term sent to Coder	System	12 Apr 2021 15:59:43
User entered 'Back ache'	Whitney West (b) (4)	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:57:29
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'un UNK 2005'	Whitney West (b) (4)	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:57:29
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:57:29
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Yes (Y)'	Whitney West (b) (4)	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:57:29
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4)	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:57:29
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'Jan 2005'	System	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '2005'	System	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	12 Apr 2021 15:59:21

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:37:57
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'UPDATED' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 18:04:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:14:50
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:52:41
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 20:27:29
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Nov 2020 20:27:29
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 20:22:57
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered '07 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '7 Aug 2020'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered '09:50' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '09:50'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '07 Aug 2020 09:50'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered '7 Aug 2020 09:50'	System	28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered '170' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '170' cm		28 Aug 2020 21:01:38
DataPoint set to visible.	System	07 Aug 2020 16:40:37

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered '74.3' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '74.3' kg		28 Aug 2020 21:01:38
DataPoint set to visible.	System	07 Aug 2020 16:40:37

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered '25.70934'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered '25.70934'	System	28 Aug 2020 21:01:38
DataPoint set to visible.	System	07 Aug 2020 16:40:37

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'kg/m2'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered 'kg/m2'	System	28 Aug 2020 21:01:38
DataPoint set to visible.	System	07 Aug 2020 16:40:37

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:37:54
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'UPDATED' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 18:04:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:14:54
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:14:54
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:52:45
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:44:29
	(b) (4), (b) (6)	10 Sep 2020 17:06:42
User entered '36.4' C		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
DataPoint Un-verified.		15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered 'Other (Other)'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
DataPoint Un-verified.		15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered 'temporal'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '61'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'bpm'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered 'bpm'	System	28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '16'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'breaths/min'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered 'breaths/min'	System	28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '115'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'mmHg'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered 'mmHg'	System	28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:52:41
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:52:41
DataPoint Verified.		10 Sep 2020 17:06:42
User entered '72'		28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered 'mmHg'	System	25 Sep 2020 18:03:58
User entered empty.	System	15 Sep 2020 23:52:41
User entered 'mmHg'	System	28 Aug 2020 21:01:38

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00

US3272078

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00

US3272078

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:46
User entered 'Yes (Y)'		28 Aug 2020 21:01:50

US3272078

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:58:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:44:30
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4) Kayla Flege (b) (4)	18 Nov 2020 23:44:30
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:46
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		07 Sep 2020 09:29:09
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 22:29:22
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:01:50

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:58:29
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:44:46
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Kayla Flege (b) (4)	18 Nov 2020 23:44:46
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4)	
	System	16 Nov 2020 20:27:37
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	16 Nov 2020 20:26:28
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered '7 Aug 2020'		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered 'Yes (Y)'		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered empty.		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered empty.		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered empty.		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered '0'		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered empty.		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:24:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:50
User entered '0'		28 Aug 2020 21:02:15

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:56
User entered 'Yes (Y)'		28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.		26 Apr 2021 19:58:36
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:44:54
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4) Kayla Flege (b) (4)	18 Nov 2020 23:44:54
DataPoint Verified.	(b) (4)	10 Sep 2020 17:06:56
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:56
User entered 'Urine (URINE)'		28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:56
User entered 'Negative (NEGATIVE)'		28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:56
User entered 'No (N)'		28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:20
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 09:26:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:02
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:56
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'confirm update' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 22:06:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:05:57
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:21:30
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:06:56
User entered empty; reason for change Data Entry Error		09 Sep 2020 22:05:57
User entered '10:09'		28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User entered empty.	System	09 Sep 2020 22:05:57
User entered '7 Aug 2020 10:09'	System	28 Aug 2020 21:02:38

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'Yes (Y)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'No (N)'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered empty.		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered '0'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered '0'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered '0'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered 'I'		28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:03:06

US3272078

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:20
User entered empty.		28 Aug 2020 21:03:06

US3272078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:32
User entered 'Yes (Y)'		28 Aug 2020 21:03:18

US3272078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:44:49
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:45:44
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 23:45:44
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:32
User entered '7 Aug 2020'		28 Aug 2020 21:03:18

US3272078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:32
User entered 'Clinic (Clinic)'		28 Aug 2020 21:03:18

US3272078

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'VISIT1'	System	28 Aug 2020 21:03:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:51:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:51:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 15:40:17
User entered '101848' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:40:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered 'No (N)'		28 Aug 2020 21:04:26

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered 'No (N)'		28 Aug 2020 21:04:26

US3272078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered 'No (N)'		28 Aug 2020 21:04:26

US3272078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered 'No (N)'		28 Aug 2020 21:04:26

US3272078

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:07:36
User entered 'No (N)'		28 Aug 2020 21:04:26

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:47
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:00
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:51:14
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:46
Data hard unlocked.	(b) (4), (b) (6)	30 Oct 2020 18:30:42
Data hard locked.	(b) (4), (b) (6)	30 Oct 2020 18:30:40
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '170' cm	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:48
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:16
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:51:19
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:51
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '74.3' kg		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:47
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:00
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:51:14
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:46
Data hard unlocked.	(b) (4), (b) (6)	30 Oct 2020 18:30:42
Data hard locked.	(b) (4), (b) (6)	30 Oct 2020 18:30:40
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '170' cm	(b) (4), (b) (6)	28 Aug 2020 21:06:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:48
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:16
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:51:19
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:51
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '74.3' kg		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User accepted default value 'Pre-Dose (PREDOSE)'		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered 'Yes (Y)'		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:01
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:45:30
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 23:45:30
DataPoint Verified.	(b) (4)	18 Nov 2020 23:45:30
User entered '7 Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 17:10:18
		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '09:50'		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered '07 Aug 2020 09:50'	System	18 Nov 2020 23:45:30
User entered '7 Aug 2020 09:50'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '36.4' C		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered 'Other (Other)'		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered 'temporal'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '61'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'bpm'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '16'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'breaths/min'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '115'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'mmHg'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '72'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'mmHg'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:47
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:00
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:51:14
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:46
Data hard unlocked.	(b) (4), (b) (6)	30 Oct 2020 18:30:42
Data hard locked.	(b) (4), (b) (6)	30 Oct 2020 18:30:40
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '170' cm	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:57:48
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:16
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:51:19
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:51:05
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:51
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '74.3' kg		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User accepted default value 'Post-Dose (POSTDOSE)'		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered 'Yes (Y)'		28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:09
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:45:30
User entered '07 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:45:30
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '11:52'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered '07 Aug 2020 11:52'	System	18 Nov 2020 23:45:30
User entered '7 Aug 2020 11:52'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '36.7' C	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '60'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'bpm'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '16'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'breaths/min'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '111'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'mmHg'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:18
User entered '76'	(b) (4), (b) (6)	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'mmHg'	System	28 Aug 2020 21:06:23

US3272078

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:06:33

US3272078

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:04
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:45:36
User entered '07 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:45:36
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:24
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:06:33

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User closed query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 11:40:44
Query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' answered with 'confirm update' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 22:07:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:07:08
User opened query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User entered empty; reason for change Data Entry Error		09 Sep 2020 22:07:08
User entered '7 Aug 2020'		28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:07:08
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User entered empty; reason for change Data Entry Error		09 Sep 2020 22:07:08
User entered 'Negative (NEGATIVE)'		28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:07:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:07:08
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:07:08
User entered '10:09'	(b) (4), (b) (6)	28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered empty.	System	09 Sep 2020 22:07:08
User entered '7 Aug 2020 10:09'	System	28 Aug 2020 21:07:05

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered empty.	Ashley Bell (b) (4)	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered empty.	Ashley Bell (b) (4)	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered '07 Aug 2020'	Ashley Bell (b) (4)	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered '11:22'	Ashley Bell (b) (4)	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered '07 Aug 2020 11:22'	System	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered 'Left Arm (LEFT ARM)'	Ashley Bell (b) (4)	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:30
User entered 'ONCE'	System	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 16:41:07

US3272078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:07:26

US3272078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:38
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:47:08
User entered '07 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:47:08
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:37
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:07:26

US3272078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:37
User entered '10:20'	(b) (4), (b) (6)	28 Aug 2020 21:07:26

US3272078

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered '07 Aug 2020 10:20'	System	18 Nov 2020 23:47:08
User entered '7 Aug 2020 10:20'	System	28 Aug 2020 21:07:26

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:49
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:47:14
User entered '07 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:47:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:41
User entered '7 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:41
User entered '10:00'	(b) (4), (b) (6)	28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered '07 Aug 2020 10:00'	System	18 Nov 2020 23:47:14
User entered '7 Aug 2020 10:00'	System	28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:41
User entered 'No (N)'		28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:41
User entered empty.		28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered empty.	System	28 Aug 2020 21:07:52

US3272078

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:10:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:07:57

US3272078

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:12
User entered 'I'	System	28 Aug 2020 21:07:57

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:48:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '443de4a5-7891-48d9-b140-2e4496f68fdf' User entered 'Yes (Y)'	System	07 Aug 2020 16:48:26
	System	07 Aug 2020 16:48:26

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:48:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '443de4a5-7891-48d9-b140-2e4496f68fdf' User entered '98.2'	System	07 Aug 2020 16:48:26
	System	07 Aug 2020 16:48:26

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:48:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '443de4a5-7891-48d9-b140-2e4496f68fdf' User entered 'No (N)'	System	07 Aug 2020 16:48:26
	System	07 Aug 2020 16:48:26

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:48:23', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '443de4a5-7891-48d9-b140-2e4496f68fdf' User entered '07 Aug 2020 11:48'	System	07 Aug 2020 16:48:26
	System	07 Aug 2020 16:48:26

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 11:42'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 14:12'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:26', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42c482b8-3324-497f-83f4-73493a867ad0' User entered 'Yes (Y)'	System	07 Aug 2020 20:50:04
	System	07 Aug 2020 20:50:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42c482b8-3324-497f-83f4-73493a867ad0' User entered '98.0'	System	07 Aug 2020 20:50:04
	System	07 Aug 2020 20:50:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42c482b8-3324-497f-83f4-73493a867ad0'	System	07 Aug 2020 20:50:04
User entered 'No (N)'	System	07 Aug 2020 20:50:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:37', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42c482b8-3324-497f-83f4-73493a867ad0' User entered '07 Aug 2020 15:47'	System	07 Aug 2020 20:50:04
	System	07 Aug 2020 20:50:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 15:07'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 2'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:05:50', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0053ba8a-1355-4cd2-8b2e-9cf81784b9d6' User entered 'Yes (Y)'	System	08 Aug 2020 17:06:02
	System	08 Aug 2020 17:06:02

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:05:54', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0053ba8a-1355-4cd2-8b2e-9cf81784b9d6' User entered '97.6'	System	08 Aug 2020 17:06:02
	System	08 Aug 2020 17:06:02

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:05:56', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0053ba8a-1355-4cd2-8b2e-9cf81784b9d6'	System	08 Aug 2020 17:06:02
User entered 'No (N)'	System	08 Aug 2020 17:06:02

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0053ba8a-1355-4cd2-8b2e-9cf81784b9d6'	System	08 Aug 2020 17:06:02
User entered '08 Aug 2020 12:06'	System	08 Aug 2020 17:06:02

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 3'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:23:51', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '18338254-5f7f-4ae6-bd96-79ff5d2f9a78'	System	09 Aug 2020 17:24:04
User entered 'Yes (Y)'	System	09 Aug 2020 17:24:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:23:55', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '18338254-5f7f-4ae6-bd96-79ff5d2f9a78' User entered '98.0'	System	09 Aug 2020 17:24:04
	System	09 Aug 2020 17:24:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:23:58', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '18338254-5f7f-4ae6-bd96-79ff5d2f9a78'	System	09 Aug 2020 17:24:04
User entered 'No (N)'	System	09 Aug 2020 17:24:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '18338254-5f7f-4ae6-bd96-79ff5d2f9a78'	System	09 Aug 2020 17:24:04
User entered '09 Aug 2020 12:24'	System	09 Aug 2020 17:24:04

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 4'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:12', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ec2fe071-4e8a-4b76-9120-eaf9b3f4520a' User entered 'Yes (Y)'	System	10 Aug 2020 17:00:23
	System	10 Aug 2020 17:00:23

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ec2fe071-4e8a-4b76-9120-eaf9b3f4520a' User entered '98.0'	System	10 Aug 2020 17:00:23
	System	10 Aug 2020 17:00:23

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ec2fe071-4e8a-4b76-9120-eaf9b3f4520a' User entered 'No (N)'	System	10 Aug 2020 17:00:23
	System	10 Aug 2020 17:00:23

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:21', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ec2fe071-4e8a-4b76-9120-eaf9b3f4520a' User entered '10 Aug 2020 12:00'	System	10 Aug 2020 17:00:23
	System	10 Aug 2020 17:00:23

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 5'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:38', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6c10852f-f094-47cd-a1fa-fbf556f04b99'	System	11 Aug 2020 19:17:50
User entered 'Yes (Y)'	System	11 Aug 2020 19:17:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:41', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6c10852f-f094-47cd-a1fa-fbf556f04b99' User entered '97.0'	System	11 Aug 2020 19:17:50
	System	11 Aug 2020 19:17:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:44', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6c10852f-f094-47cd-a1fa-fbf556f04b99'	System	11 Aug 2020 19:17:50
User entered 'No (N)'	System	11 Aug 2020 19:17:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:46', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6c10852f-f094-47cd-a1fa-fbf556f04b99'	System	11 Aug 2020 19:17:50
User entered '11 Aug 2020 14:17'	System	11 Aug 2020 19:17:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 6'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:10', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d59218e-dc3a-4291-8e4f-f7809ab62771' User entered 'Yes (Y)'	System	12 Aug 2020 17:00:21
	System	12 Aug 2020 17:00:21

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:14', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d59218e-dc3a-4291-8e4f-f7809ab62771' User entered '97.0'	System	12 Aug 2020 17:00:21
	System	12 Aug 2020 17:00:21

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d59218e-dc3a-4291-8e4f-f7809ab62771' User entered 'No (N)'	System	12 Aug 2020 17:00:21
	System	12 Aug 2020 17:00:21

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d59218e-dc3a-4291-8e4f-f7809ab62771' User entered '12 Aug 2020 12:00'	System	12 Aug 2020 17:00:21
	System	12 Aug 2020 17:00:21

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 7'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:36', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ba7a334a-707a-4814-a45f-98af6904ddf9' User entered 'Yes (Y)'	System	13 Aug 2020 18:05:50
	System	13 Aug 2020 18:05:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ba7a334a-707a-4814-a45f-98af6904ddf9' User entered '97.5'	System	13 Aug 2020 18:05:50
	System	13 Aug 2020 18:05:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:45', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ba7a334a-707a-4814-a45f-98af6904ddf9'	System	13 Aug 2020 18:05:50
User entered 'No (N)'	System	13 Aug 2020 18:05:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:49', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ba7a334a-707a-4814-a45f-98af6904ddf9' User entered '13 Aug 2020 13:05'	System	13 Aug 2020 18:05:50
	System	13 Aug 2020 18:05:50

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7c66bda0-2def-4061-ba1f-9b57b2f47f4c' User entered 'None (1)'	System	07 Aug 2020 16:46:53
	System	07 Aug 2020 16:46:53

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:32', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7c66bda0-2def-4061-ba1f-9b57b2f47f4c' User entered 'No (N)'	System	07 Aug 2020 16:46:53
	System	07 Aug 2020 16:46:53

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:37', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7c66bda0-2def-4061-ba1f-9b57b2f47f4c' User entered 'No (N)'	System	07 Aug 2020 16:46:53
	System	07 Aug 2020 16:46:53

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7c66bda0-2def-4061-ba1f-9b57b2f47f4c' User entered 'None (1)'	System	07 Aug 2020 16:46:53
	System	07 Aug 2020 16:46:53

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:49', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7c66bda0-2def-4061-ba1f-9b57b2f47f4c' User entered '07 Aug 2020 11:46'	System	07 Aug 2020 16:46:53
	System	07 Aug 2020 16:46:53

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 11:42'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 14:12'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '20e60517-242a-4c6f-96bb-05a86de39e62'	System	07 Aug 2020 20:50:32
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 20:50:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:45', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '20e60517-242a-4c6f-96bb-05a86de39e62' User entered 'No (N)'	System	07 Aug 2020 20:50:32
	System	07 Aug 2020 20:50:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:47:55', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '20e60517-242a-4c6f-96bb-05a86de39e62' User entered 'No (N)'	System	07 Aug 2020 20:50:32
	System	07 Aug 2020 20:50:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '20e60517-242a-4c6f-96bb-05a86de39e62'	System	07 Aug 2020 20:50:32
User entered 'None (1)'	System	07 Aug 2020 20:50:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '20e60517-242a-4c6f-96bb-05a86de39e62' User entered '07 Aug 2020 15:48'	System	07 Aug 2020 20:50:32
	System	07 Aug 2020 20:50:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 15:07'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 2'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '148540d7-68f9-4205-acab-fa99c775dfb7'	System	08 Aug 2020 17:06:16
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 17:06:16

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '148540d7-68f9-4205-acab-fa99c775dfb7'	System	08 Aug 2020 17:06:16
User entered 'No (N)'	System	08 Aug 2020 17:06:16

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '148540d7-68f9-4205-acab-fa99c775dfb7'	System	08 Aug 2020 17:06:16
User entered 'No (N)'	System	08 Aug 2020 17:06:16

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:11', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '148540d7-68f9-4205-acab-fa99c775dfb7'	System	08 Aug 2020 17:06:16
User entered 'None (1)'	System	08 Aug 2020 17:06:16

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:14', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '148540d7-68f9-4205-acab-fa99c775dfb7'	System	08 Aug 2020 17:06:16
User entered '08 Aug 2020 12:06'	System	08 Aug 2020 17:06:16

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 3'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:05', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'da11c3ba-b5d7-4f17-bbc5-36c1e6b31954'	System	09 Aug 2020 17:24:20
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 17:24:20

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:07', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'da11c3ba-b5d7-4f17-bbc5-36c1e6b31954' User entered 'No (N)'	System	09 Aug 2020 17:24:20
	System	09 Aug 2020 17:24:20

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'da11c3ba-b5d7-4f17-bbc5-36c1e6b31954' User entered 'No (N)'	System	09 Aug 2020 17:24:20
	System	09 Aug 2020 17:24:20

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:12', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'da11c3ba-b5d7-4f17-bbc5-36c1e6b31954' User entered 'None (1)'	System	09 Aug 2020 17:24:20
	System	09 Aug 2020 17:24:20

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'da11c3ba-b5d7-4f17-bbc5-36c1e6b31954' User entered '09 Aug 2020 12:24'	System	09 Aug 2020 17:24:20
	System	09 Aug 2020 17:24:20

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 4'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '374ea283-31af-488a-b121-26873b62c538'	System	10 Aug 2020 17:00:38
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 17:00:38

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:27', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '374ea283-31af-488a-b121-26873b62c538'	System	10 Aug 2020 17:00:38
User entered 'No (N)'	System	10 Aug 2020 17:00:38

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:29', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '374ea283-31af-488a-b121-26873b62c538'	System	10 Aug 2020 17:00:38
User entered 'No (N)'	System	10 Aug 2020 17:00:38

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '374ea283-31af-488a-b121-26873b62c538'	System	10 Aug 2020 17:00:38
User entered 'None (1)'	System	10 Aug 2020 17:00:38

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '374ea283-31af-488a-b121-26873b62c538'	System	10 Aug 2020 17:00:38
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 17:00:38

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 5'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:49', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd1f755d3-eefc-429e-aba8-2dac23736a14' User entered 'None (1)'	System	11 Aug 2020 19:18:00
	System	11 Aug 2020 19:18:00

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:51', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd1f755d3-eefc-429e-aba8-2dac23736a14' User entered 'No (N)'	System	11 Aug 2020 19:18:00
	System	11 Aug 2020 19:18:00

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:53', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd1f755d3-eefc-429e-aba8-2dac23736a14' User entered 'No (N)'	System	11 Aug 2020 19:18:00
	System	11 Aug 2020 19:18:00

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:54', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd1f755d3-eefc-429e-aba8-2dac23736a14' User entered 'None (1)'	System	11 Aug 2020 19:18:00
	System	11 Aug 2020 19:18:00

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:17:56', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd1f755d3-eefc-429e-aba8-2dac23736a14' User entered '11 Aug 2020 14:17'	System	11 Aug 2020 19:18:00
	System	11 Aug 2020 19:18:00

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 6'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '336707d0-e66f-4782-9707-6ec5e1fd182e' User entered 'None (1)'	System	12 Aug 2020 17:00:32
	System	12 Aug 2020 17:00:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:23', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '336707d0-e66f-4782-9707-6ec5e1fd182e' User entered 'No (N)'	System	12 Aug 2020 17:00:32
	System	12 Aug 2020 17:00:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:24', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '336707d0-e66f-4782-9707-6ec5e1fd182e' User entered 'No (N)'	System	12 Aug 2020 17:00:32
	System	12 Aug 2020 17:00:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:26', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '336707d0-e66f-4782-9707-6ec5e1fd182e' User entered 'None (1)'	System	12 Aug 2020 17:00:32
	System	12 Aug 2020 17:00:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:28', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '336707d0-e66f-4782-9707-6ec5e1fd182e' User entered '12 Aug 2020 12:00'	System	12 Aug 2020 17:00:32
	System	12 Aug 2020 17:00:32

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 7'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:52', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c06daf48-6ef2-4079-b4fa-23126585a5ef'	System	13 Aug 2020 18:06:01
User entered 'None (1)'	System	13 Aug 2020 18:06:01

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:53', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c06daf48-6ef2-4079-b4fa-23126585a5ef' User entered 'No (N)'	System	13 Aug 2020 18:06:01
	System	13 Aug 2020 18:06:01

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:55', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c06daf48-6ef2-4079-b4fa-23126585a5ef' User entered 'No (N)'	System	13 Aug 2020 18:06:01
	System	13 Aug 2020 18:06:01

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:56', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c06daf48-6ef2-4079-b4fa-23126585a5ef' User entered 'None (1)'	System	13 Aug 2020 18:06:01
	System	13 Aug 2020 18:06:01

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:05:58', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c06daf48-6ef2-4079-b4fa-23126585a5ef' User entered '13 Aug 2020 13:05'	System	13 Aug 2020 18:06:01
	System	13 Aug 2020 18:06:01

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:57', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'None (0)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:46:59', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'None (0)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:47:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'None (0)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:47:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'None (0)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:47:05', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'None (0)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:47:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'None (0)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:47:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered 'No (N)'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T11:47:14', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0a52a888-002c-4572-b740-2256bcff851e' User entered '07 Aug 2020 11:47'	System	07 Aug 2020 16:47:19
	System	07 Aug 2020 16:47:19

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 11:42'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 14:12'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29' User entered 'None (0)'	System	07 Aug 2020 20:50:33
	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29'	System	07 Aug 2020 20:50:33
User entered 'No interference with activity (1)'	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29' User entered 'None (0)'	System	07 Aug 2020 20:50:33
	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29' User entered 'None (0)'	System	07 Aug 2020 20:50:33
	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:19', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29' User entered 'None (0)'	System	07 Aug 2020 20:50:33
	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:21', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29'	System	07 Aug 2020 20:50:33
User entered 'None (0)'	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:24', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29'	System	07 Aug 2020 20:50:33
User entered 'No (N)'	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-07T15:48:26', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '52b63f68-ff7d-4a75-94f7-f0e4d7f8cd29'	System	07 Aug 2020 20:50:33
User entered '07 Aug 2020 15:48'	System	07 Aug 2020 20:50:33

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Aug 2020 15:07'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 2'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11'	System	08 Aug 2020 17:06:34
User entered 'No interference with activity (1)'	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11'	System	08 Aug 2020 17:06:34
User entered 'No interference with activity (1)'	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11' User entered 'None (0)'	System	08 Aug 2020 17:06:34
	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:24', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11' User entered 'None (0)'	System	08 Aug 2020 17:06:34
	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11' User entered 'None (0)'	System	08 Aug 2020 17:06:34
	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:27', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11' User entered 'None (0)'	System	08 Aug 2020 17:06:34
	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:29', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11' User entered 'No (N)'	System	08 Aug 2020 17:06:34
	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-08T12:06:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'cdc94208-39ae-4947-a1d7-839a6a524e11' User entered '08 Aug 2020 12:06'	System	08 Aug 2020 17:06:34
	System	08 Aug 2020 17:06:34

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 3'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'None (0)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'None (0)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:23', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'None (0)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'None (0)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:27', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'None (0)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'None (0)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:32', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered 'No (N)'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-09T12:24:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9ed3f9f2-3d7f-4125-ad1d-51d77ed75014' User entered '09 Aug 2020 12:24'	System	09 Aug 2020 17:24:36
	System	09 Aug 2020 17:24:36

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 4'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:37', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'None (0)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:39', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'None (0)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:41', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'None (0)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:42', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'None (0)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:44', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'None (0)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:46', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'None (0)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:48', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered 'No (N)'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-10T12:00:50', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '11866760-902b-4e51-baa7-9b485051ca6d' User entered '10 Aug 2020 12:00'	System	10 Aug 2020 17:00:52
	System	10 Aug 2020 17:00:52

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 5'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'None (0)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'None (0)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:02', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'None (0)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'None (0)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:05', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'None (0)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'None (0)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered 'No (N)'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-11T14:18:10', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '62dad120-54c7-4a8d-8fb8-b63759f23abe' User entered '11 Aug 2020 14:18'	System	11 Aug 2020 19:18:11
	System	11 Aug 2020 19:18:11

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 6'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'None (0)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:35', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'None (0)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:36', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'None (0)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:38', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'None (0)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:39', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'None (0)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:41', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'None (0)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered 'No (N)'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-12T12:00:45', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e14f016b-3eea-417a-9972-455493bd6fc3' User entered '12 Aug 2020 12:00'	System	12 Aug 2020 17:00:54
	System	12 Aug 2020 17:00:54

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 7'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'None (0)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'None (0)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'None (0)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'None (0)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'None (0)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:11', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'None (0)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered 'No (N)'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-08-13T13:06:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'd3301b9c-75ba-489d-9f67-3752acc1e750' User entered '13 Aug 2020 13:06'	System	13 Aug 2020 18:06:23
	System	13 Aug 2020 18:06:23

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:41:07

US3272078

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:00:33
User entered 'Yes (Y)'		28 Aug 2020 21:08:17

US3272078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:00:33
User entered '14 Aug 2020'		28 Aug 2020 21:08:17

US3272078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:00:33
User entered 'Contact Made (CONTACT MADE)'		28 Aug 2020 21:08:17

US3272078

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:00:33
User entered empty.		28 Aug 2020 21:08:17

US3272078

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:08:21

US3272078

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:29
User entered 'I'	System	28 Aug 2020 21:08:21

US3272078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:07
User entered 'Yes (Y)'		28 Aug 2020 21:08:40

US3272078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:01:38
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:48:19
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 23:48:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:07
User entered '21 Aug 2020'		28 Aug 2020 21:08:40

US3272078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:07
User entered 'Contact Made (CONTACT MADE)'		28 Aug 2020 21:08:40

US3272078

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:08:40

US3272078

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:15
User entered 'Yes (Y)'		28 Aug 2020 21:08:45

US3272078

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:22
User entered 'I'	System	28 Aug 2020 21:08:45

US3272078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:23
User entered 'Yes (Y)'		28 Aug 2020 21:10:19

US3272078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:15:10
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		-04 Dec 2020 04:25:46
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct.' (Site from System).	Kayla Flege (b) (4)	18 Nov 2020 23:52:03
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Nov 2020 23:49:02
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:49:02
User entered '26 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:49:02
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:23
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 21:10:33
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Aug 2020 21:10:33
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 21:10:33

US3272078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 21:10:19
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:10:19

US3272078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:23
User entered 'Contact Made (CONTACT MADE)'		28 Aug 2020 21:10:19

US3272078

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:23
User entered empty.		28 Aug 2020 21:10:19

US3272078

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:10:38

US3272078

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:03
User entered 'I'	System	28 Aug 2020 21:10:38

US3272078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 22:29:22

US3272078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:36
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 22:29:22

US3272078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 22:29:22

US3272078

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'VISIT2'	System	04 Sep 2020 22:29:22

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User accepted default value 'Pre-Dose (PREDOSE)'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:16:16
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:52:25
User entered '04 Sep 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:52:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '08:59'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered '04 Sep 2020 08:59'	System	18 Nov 2020 23:52:25
User entered '4 Sep 2020 08:59'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '36.9' C	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '75'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'bpm'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '14'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'breaths/min'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '103'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'mmHg'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '71'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'mmHg'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User accepted default value 'Post-Dose (POSTDOSE)'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered 'Yes (Y)'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:16:25
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:52:25
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 23:52:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '4 Sep 2020'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '10:43'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered '04 Sep 2020 10:43'	System	18 Nov 2020 23:52:25
User entered '4 Sep 2020 10:43'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '36.8' C		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '63'	(b) (4), (b) (6)	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'bpm'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '12'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'breaths/min'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '106'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'mmHg'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:41
User entered '74'		04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'mmHg'	System	04 Sep 2020 22:30:44

US3272078

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:47
User entered 'Yes (Y)'		04 Sep 2020 22:30:54

US3272078

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:17:10
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:53:34
User entered '04 Sep 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:53:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:11:47
User entered '4 Sep 2020'		04 Sep 2020 22:30:54

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:54
User entered 'Yes (Y)'		04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:18:15
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:53:42
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Kayla Flege (b) (4)	18 Nov 2020 23:53:42
	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:11:54
User entered '4 Sep 2020'		04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:54
User entered 'Urine (URINE)'		04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:54
User entered 'Negative (NEGATIVE)'		04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:54
User entered 'No (N)'		04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:58:16
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).		16 Sep 2020 11:40:27
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:58
DataPoint Verified.		10 Sep 2020 17:11:54
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'confirm update' (Site from DM).		09 Sep 2020 22:07:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:07:21
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).		09 Sep 2020 21:21:23
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:11:54
User entered empty; reason for change Data Entry Error		09 Sep 2020 22:07:21
User entered '08:52'		04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:24:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered empty.	System	09 Sep 2020 22:07:21
User entered '4 Sep 2020 08:52'	System	04 Sep 2020 22:31:16

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered 'Yes (Y)'		04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered empty.		04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered empty.		04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered '04 Sep 2020'		04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered '09:55'		04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered '04 Sep 2020 09:55'	System	04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:13
User entered 'ONCE'	System	04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 15:01:12

US3272078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:17
User entered 'Yes (Y)'		04 Sep 2020 22:31:31

US3272078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:19:14
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Nov 2020 23:53:48
User entered '04 Sep 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:53:48
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:17
User entered '4 Sep 2020'		04 Sep 2020 22:31:31

US3272078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:17
User entered '09:12'		04 Sep 2020 22:31:31

US3272078

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered '04 Sep 2020 09:12'	System	18 Nov 2020 23:53:48
User entered '4 Sep 2020 09:12'	System	04 Sep 2020 22:31:31

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:15:33
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, " sample collected" however, swab collected on 04-SEP-2020 at Visit 2 Day 29 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:56:39
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, " sample collected"; however, swab collected on 04-SEP-2020 at Visit 2 Day 29 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'sample has been shipped. no sample for the subject on site.' (Site from DM).	Kayla Flege (b) (4)	09 Dec 2020 20:53:26
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, " sample collected"; however, swab collected on 04-SEP-2020 at Visit 2 Day 29 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:49:42
User closed query 'Per GCL Lab recon: Swab: Sample collection date 04-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD PORTAL Kindly confirm if swab sample was collected on 04-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:18

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab recon: Swab: Sample collection date 04-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD PORTAL Kindly confirm if swab sample was collected on 04-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal. ' answered with 'sample collected' (Site from DM). DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	18 Nov 2020 23:54:31
User entered '04 Sep 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Nov 2020 23:54:25
User opened query 'Per GCL Lab recon: Swab: Sample collection date 04-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD PORTAL Kindly confirm if swab sample was collected on 04-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 05:18:11
User entered '4 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:12:20
		04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:20
User entered '09:04'	(b) (4), (b) (6)	04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered '04 Sep 2020 09:04'	System	18 Nov 2020 23:54:25
User entered '4 Sep 2020 09:04'	System	04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:20
User entered 'No (N)'		04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:20
User entered empty.		04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered empty.	System	04 Sep 2020 22:31:43

US3272078

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:12:24
User entered 'Yes (Y)'		04 Sep 2020 22:31:47

US3272078

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:53
User entered 'I'	System	04 Sep 2020 22:31:47

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:43:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '755a72e7-696f-42d9-b366-681508ec5204' User entered 'Yes (Y)'	System	04 Sep 2020 15:43:20
	System	04 Sep 2020 15:43:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:43:11', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '755a72e7-696f-42d9-b366-681508ec5204' User entered '98.2'	System	04 Sep 2020 15:43:20
	System	04 Sep 2020 15:43:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:43:14', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '755a72e7-696f-42d9-b366-681508ec5204' User entered 'No (N)'	System	04 Sep 2020 15:43:20
	System	04 Sep 2020 15:43:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:43:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '755a72e7-696f-42d9-b366-681508ec5204' User entered '04 Sep 2020 10:43'	System	04 Sep 2020 15:43:20
	System	04 Sep 2020 15:43:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 10:15'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 12:45'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '55cacbbb-b92c-4231-973b-12bbdea93a97' User entered 'Yes (Y)'	System	05 Sep 2020 14:45:38
	System	05 Sep 2020 14:45:38

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '55cacbbb-b92c-4231-973b-12bbdea93a97' User entered '98.1'	System	05 Sep 2020 14:45:38
	System	05 Sep 2020 14:45:38

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:28', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '55cacbbb-b92c-4231-973b-12bbdea93a97'	System	05 Sep 2020 14:45:38
User entered 'Yes (Y)'	System	05 Sep 2020 14:45:38

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '55cacbbb-b92c-4231-973b-12bbdea93a97' User entered '0'	System	05 Sep 2020 14:45:38
	System	05 Sep 2020 14:45:38

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Reported taking Ibuprofen 2-200mg twice that day for a headache.' (Site from System).		09 Nov 2020 18:27:45
User opened query 'Per the participant response, medication was taken to prevent 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).	System	05 Sep 2020 14:45:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '55cacbbb-b92c-4231-973b-12bbdea93a97'	System	05 Sep 2020 14:45:38
User entered '1'	System	05 Sep 2020 14:45:38

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:36', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '55cacbbb-b92c-4231-973b-12bbdea93a97' User entered '05 Sep 2020 09:45'	System	05 Sep 2020 14:45:38
	System	05 Sep 2020 14:45:38

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 13:40'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 2'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:05', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ffad3593-7460-437c-8310-5d08dbc4949d' User entered 'Yes (Y)'	System	06 Sep 2020 03:19:15
	System	06 Sep 2020 03:19:15

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ffad3593-7460-437c-8310-5d08dbc4949d' User entered '97.6'	System	06 Sep 2020 03:19:15
	System	06 Sep 2020 03:19:15

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:10', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ffad3593-7460-437c-8310-5d08dbc4949d'	System	06 Sep 2020 03:19:15
User entered 'No (N)'	System	06 Sep 2020 03:19:15

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:12', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'ffad3593-7460-437c-8310-5d08dbc4949d' User entered '05 Sep 2020 22:19'	System	06 Sep 2020 03:19:15
	System	06 Sep 2020 03:19:15

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 3'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '58105a5a-9650-4d02-bb05-5bcee09ff486' User entered 'Yes (Y)'	System	06 Sep 2020 17:00:20
	System	06 Sep 2020 17:00:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:12', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '58105a5a-9650-4d02-bb05-5bcee09ff486' User entered '98.8'	System	06 Sep 2020 17:00:20
	System	06 Sep 2020 17:00:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '58105a5a-9650-4d02-bb05-5bcee09ff486'	System	06 Sep 2020 17:00:20
User entered 'No (N)'	System	06 Sep 2020 17:00:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '58105a5a-9650-4d02-bb05-5bcee09ff486' User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:00:20
	System	06 Sep 2020 17:00:20

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 4'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:18:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f9859d49-4fbd-401e-90b0-6c99bd3a4b15' User entered 'Yes (Y)'	System	07 Sep 2020 20:18:55
	System	07 Sep 2020 20:18:55

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:18:49', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f9859d49-4fbd-401e-90b0-6c99bd3a4b15' User entered '97.6'	System	07 Sep 2020 20:18:55
	System	07 Sep 2020 20:18:55

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:18:51', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f9859d49-4fbd-401e-90b0-6c99bd3a4b15' User entered 'No (N)'	System	07 Sep 2020 20:18:55
	System	07 Sep 2020 20:18:55

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:18:53', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f9859d49-4fbd-401e-90b0-6c99bd3a4b15' User entered '07 Sep 2020 15:18'	System	07 Sep 2020 20:18:55
	System	07 Sep 2020 20:18:55

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 5'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:26', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47871ddb-0338-42b5-8572-0fcab08e6b16' User entered 'Yes (Y)'	System	08 Sep 2020 17:00:56
	System	08 Sep 2020 17:00:56

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47871ddb-0338-42b5-8572-0fcab08e6b16' User entered '97.5'	System	08 Sep 2020 17:00:56
	System	08 Sep 2020 17:00:56

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:33', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47871ddb-0338-42b5-8572-0fcab08e6b16' User entered 'No (N)'	System	08 Sep 2020 17:00:56
	System	08 Sep 2020 17:00:56

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47871ddb-0338-42b5-8572-0fcab08e6b16' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:00:56
	System	08 Sep 2020 17:00:56

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 6'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:41', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f94d998e-346c-4801-a32b-bc859c6483f4' User entered 'Yes (Y)'	System	09 Sep 2020 17:05:58
	System	09 Sep 2020 17:05:58

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:46', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f94d998e-346c-4801-a32b-bc859c6483f4' User entered '98.4'	System	09 Sep 2020 17:05:58
	System	09 Sep 2020 17:05:58

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:48', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f94d998e-346c-4801-a32b-bc859c6483f4' User entered 'No (N)'	System	09 Sep 2020 17:05:58
	System	09 Sep 2020 17:05:58

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:50', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f94d998e-346c-4801-a32b-bc859c6483f4' User entered '09 Sep 2020 12:05'	System	09 Sep 2020 17:05:58
	System	09 Sep 2020 17:05:58

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 7'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:36', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f46766d2-cfc5-477c-9f16-f148ce0adaaa' User entered 'Yes (Y)'	System	10 Sep 2020 22:45:50
	System	10 Sep 2020 22:45:50

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:41', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f46766d2-cfc5-477c-9f16-f148ce0adaaa' User entered '97.6'	System	10 Sep 2020 22:45:50
	System	10 Sep 2020 22:45:50

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f46766d2-cfc5-477c-9f16-f148ce0adaaa'	System	10 Sep 2020 22:45:50
User entered 'No (N)'	System	10 Sep 2020 22:45:50

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:44', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f46766d2-cfc5-477c-9f16-f148ce0adaaa'	System	10 Sep 2020 22:45:50
User entered '10 Sep 2020 17:45'	System	10 Sep 2020 22:45:50

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a2e3e730-9110-4800-b182-d9c11fe64a6a' User entered 'None (1)'	System	04 Sep 2020 15:46:16
	System	04 Sep 2020 15:46:16

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a2e3e730-9110-4800-b182-d9c11fe64a6a' User entered 'No (N)'	System	04 Sep 2020 15:46:16
	System	04 Sep 2020 15:46:16

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a2e3e730-9110-4800-b182-d9c11fe64a6a' User entered 'No (N)'	System	04 Sep 2020 15:46:16
	System	04 Sep 2020 15:46:16

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:10', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a2e3e730-9110-4800-b182-d9c11fe64a6a' User entered 'None (1)'	System	04 Sep 2020 15:46:16
	System	04 Sep 2020 15:46:16

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:12', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a2e3e730-9110-4800-b182-d9c11fe64a6a' User entered '04 Sep 2020 10:46'	System	04 Sep 2020 15:46:16
	System	04 Sep 2020 15:46:16

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 10:15'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 12:45'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3041cc4d-8734-4f24-a97e-ebf68ec9a656'	System	05 Sep 2020 14:45:53
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 14:45:53

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:44', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3041cc4d-8734-4f24-a97e-ebf68ec9a656' User entered 'No (N)'	System	05 Sep 2020 14:45:53
	System	05 Sep 2020 14:45:53

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:46', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3041cc4d-8734-4f24-a97e-ebf68ec9a656'	System	05 Sep 2020 14:45:53
User entered 'No (N)'	System	05 Sep 2020 14:45:53

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:48', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3041cc4d-8734-4f24-a97e-ebf68ec9a656'	System	05 Sep 2020 14:45:53
User entered 'None (1)'	System	05 Sep 2020 14:45:53

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:50', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3041cc4d-8734-4f24-a97e-ebf68ec9a656' User entered '05 Sep 2020 09:45'	System	05 Sep 2020 14:45:53
	System	05 Sep 2020 14:45:53

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 13:40'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 2'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f5bbdbc0-1317-4b48-9a84-1363292f0481'	System	06 Sep 2020 03:19:29
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 03:19:29

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f5bbbd0-1317-4b48-9a84-1363292f0481' User entered 'No (N)'	System	06 Sep 2020 03:19:29
	System	06 Sep 2020 03:19:29

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f5bbdbc0-1317-4b48-9a84-1363292f0481' User entered 'No (N)'	System	06 Sep 2020 03:19:29
	System	06 Sep 2020 03:19:29

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:23', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f5bbdbc0-1317-4b48-9a84-1363292f0481' User entered 'None (1)'	System	06 Sep 2020 03:19:29
	System	06 Sep 2020 03:19:29

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'f5bbdbc0-1317-4b48-9a84-1363292f0481' User entered '05 Sep 2020 22:19'	System	06 Sep 2020 03:19:29
	System	06 Sep 2020 03:19:29

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 3'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6'	System	06 Sep 2020 17:01:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:24', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6' User entered 'Yes (Y)'	System	06 Sep 2020 17:01:09
	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:33', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6' User entered '18'	System	06 Sep 2020 17:01:09
	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:35', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6' User entered 'Yes (Y)'	System	06 Sep 2020 17:01:09
	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:45', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6' User entered '14'	System	06 Sep 2020 17:01:09
	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:47', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6'	System	06 Sep 2020 17:01:09
User entered 'None (1)'	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:54', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '57fa5a33-19e5-413f-9d1e-cea854d9d3a6' User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:01:09
	System	06 Sep 2020 17:01:09

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 4'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:18:57', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63'	System	07 Sep 2020 20:19:21
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63' User entered 'Yes (Y)'	System	07 Sep 2020 20:19:21
	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63' User entered '8'	System	07 Sep 2020 20:19:21
	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63' User entered 'Yes (Y)'	System	07 Sep 2020 20:19:21
	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63' User entered '8'	System	07 Sep 2020 20:19:21
	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63'	System	07 Sep 2020 20:19:21
User entered 'None (1)'	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'c9f100d0-f708-46c3-8828-57da75fe8e63'	System	07 Sep 2020 20:19:21
User entered '07 Sep 2020 15:19'	System	07 Sep 2020 20:19:21

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 5'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:39', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '836327e4-cba4-4bf3-935f-d563f53aeb13'	System	08 Sep 2020 17:01:32
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 17:01:32

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:40', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '836327e4-cba4-4bf3-935f-d563f53aeb13' User entered 'No (N)'	System	08 Sep 2020 17:01:32
	System	08 Sep 2020 17:01:32

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:42', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '836327e4-cba4-4bf3-935f-d563f53aeb13'	System	08 Sep 2020 17:01:32
User entered 'Yes (Y)'	System	08 Sep 2020 17:01:32

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:45', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '836327e4-cba4-4bf3-935f-d563f53aeb13' User entered '8'	System	08 Sep 2020 17:01:32
	System	08 Sep 2020 17:01:32

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:47', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '836327e4-cba4-4bf3-935f-d563f53aeb13'	System	08 Sep 2020 17:01:32
User entered 'None (1)'	System	08 Sep 2020 17:01:32

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:50', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '836327e4-cba4-4bf3-935f-d563f53aeb13' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:01:32
	System	08 Sep 2020 17:01:32

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 6'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:53', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '390921c2-f3b1-4865-a063-5607a3143c4d'	System	09 Sep 2020 17:06:08
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 17:06:08

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:55', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '390921c2-f3b1-4865-a063-5607a3143c4d' User entered 'No (N)'	System	09 Sep 2020 17:06:08
	System	09 Sep 2020 17:06:08

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:57', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '390921c2-f3b1-4865-a063-5607a3143c4d' User entered 'No (N)'	System	09 Sep 2020 17:06:08
	System	09 Sep 2020 17:06:08

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:05:59', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '390921c2-f3b1-4865-a063-5607a3143c4d' User entered 'None (1)'	System	09 Sep 2020 17:06:08
	System	09 Sep 2020 17:06:08

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '390921c2-f3b1-4865-a063-5607a3143c4d' User entered '09 Sep 2020 12:06'	System	09 Sep 2020 17:06:08
	System	09 Sep 2020 17:06:08

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 7'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:47', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9c0ba5ce-6464-4d66-b580-44f1676f4d2c' User entered 'None (1)'	System	10 Sep 2020 22:45:56
	System	10 Sep 2020 22:45:56

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:49', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9c0ba5ce-6464-4d66-b580-44f1676f4d2c' User entered 'No (N)'	System	10 Sep 2020 22:45:56
	System	10 Sep 2020 22:45:56

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:51', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9c0ba5ce-6464-4d66-b580-44f1676f4d2c' User entered 'No (N)'	System	10 Sep 2020 22:45:56
	System	10 Sep 2020 22:45:56

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:52', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9c0ba5ce-6464-4d66-b580-44f1676f4d2c' User entered 'None (1)'	System	10 Sep 2020 22:45:56
	System	10 Sep 2020 22:45:56

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:54', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '9c0ba5ce-6464-4d66-b580-44f1676f4d2c' User entered '10 Sep 2020 17:45'	System	10 Sep 2020 22:45:56
	System	10 Sep 2020 22:45:56

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:14', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'None (0)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'None (0)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'None (0)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'None (0)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:19', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'None (0)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'None (0)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered 'No (N)'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-04T10:46:24', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '8d4a3852-b544-4103-8735-ae182a06981e' User entered '04 Sep 2020 10:46'	System	04 Sep 2020 15:46:27
	System	04 Sep 2020 15:46:27

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 10:15'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 12:45'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:53', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'None (0)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:54', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'None (0)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:55', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'None (0)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:56', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'None (0)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:58', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'None (0)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:45:59', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'None (0)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:46:02', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered 'No (N)'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T09:46:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '47934631-1300-4482-8d6e-899e6d6def47' User entered '05 Sep 2020 09:46'	System	05 Sep 2020 14:46:05
	System	05 Sep 2020 14:46:05

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '04 Sep 2020 13:40'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 2'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:29', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'No interference with activity (1)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:31', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'None (0)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:32', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'None (0)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'None (0)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:36', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'None (0)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:38', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'None (0)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:40', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered 'No (N)'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-05T22:19:42', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5e128d12-5c94-45c6-b246-aaf9b138360e' User entered '05 Sep 2020 22:19'	System	06 Sep 2020 03:19:45
	System	06 Sep 2020 03:19:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 3'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:00:57', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1'	System	06 Sep 2020 17:01:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1' User entered 'No interference with activity (1)'	System	06 Sep 2020 17:01:45
	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:02', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1' User entered 'No interference with activity (1)'	System	06 Sep 2020 17:01:45
	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1' User entered 'No interference with activity (1)'	System	06 Sep 2020 17:01:45
	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:07', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1'	System	06 Sep 2020 17:01:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1' User entered 'No interference with activity (1)'	System	06 Sep 2020 17:01:45
	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:11', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1' User entered 'No (N)'	System	06 Sep 2020 17:01:45
	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-06T12:01:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'dcbf57cd-498a-4835-a606-e0cb5be586e1' User entered '06 Sep 2020 12:01'	System	06 Sep 2020 17:01:45
	System	06 Sep 2020 17:01:45

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 4'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e'	System	07 Sep 2020 20:19:35
User entered 'No interference with activity (1)'	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered 'None (0)'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:24', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered 'None (0)'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered 'None (0)'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:27', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered 'None (0)'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:30', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered 'None (0)'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:32', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered 'No (N)'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-07T15:19:34', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '19f4ac4f-60d8-445e-9e68-65ff5024573e' User entered '07 Sep 2020 15:19'	System	07 Sep 2020 20:19:35
	System	07 Sep 2020 20:19:35

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 5'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:53', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce'	System	08 Sep 2020 17:01:58
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:54', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce'	System	08 Sep 2020 17:01:58
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:57', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce' User entered 'Some interference with activity (2)'	System	08 Sep 2020 17:01:58
	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:00:59', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce' User entered 'Some interference with activity (2)'	System	08 Sep 2020 17:01:58
	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:01:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce' User entered 'None (0)'	System	08 Sep 2020 17:01:58
	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:01:02', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce' User entered 'None (0)'	System	08 Sep 2020 17:01:58
	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:01:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce' User entered 'No (N)'	System	08 Sep 2020 17:01:58
	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-08T12:01:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b03edd0c-9096-4a4e-b853-fa940a0d56ce' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 17:01:58
	System	08 Sep 2020 17:01:58

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 6'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e' User entered 'None (0)'	System	09 Sep 2020 17:06:18
	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e'	System	09 Sep 2020 17:06:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:08', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e' User entered 'No interference with activity (1)'	System	09 Sep 2020 17:06:18
	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e'	System	09 Sep 2020 17:06:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:11', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e' User entered 'None (0)'	System	09 Sep 2020 17:06:18
	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e'	System	09 Sep 2020 17:06:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e' User entered 'No (N)'	System	09 Sep 2020 17:06:18
	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-09T12:06:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '375e7685-c3fc-4fd1-8f19-ff44ad033f5e' User entered '09 Sep 2020 12:06'	System	09 Sep 2020 17:06:18
	System	09 Sep 2020 17:06:18

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	04 Sep 2020 15:01:12
User entered 'Day 7'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:57', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'None (0)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:58', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'None (0)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:45:59', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'None (0)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:46:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'None (0)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:46:02', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'None (0)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:46:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'None (0)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:46:05', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered 'No (N)'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-09-10T17:46:07', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3dd0dc38-7067-4202-9ea6-d6cf18b02247' User entered '10 Sep 2020 17:46'	System	10 Sep 2020 22:46:12
	System	10 Sep 2020 22:46:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:01:12

US3272078

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:01:12

US3272078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:06:30

US3272078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:34
User entered '11 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 20:06:30

US3272078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 20:06:30

US3272078

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:34
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:06:30

US3272078

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:06:32

US3272078

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:17
User entered 'I'	System	18 Sep 2020 20:06:32

US3272078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:06:41

US3272078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:44
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 20:06:41

US3272078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 20:06:41

US3272078

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:44
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 20:06:41

US3272078

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 20:06:45

US3272078

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:37
User entered 'I'	System	18 Sep 2020 20:06:45

US3272078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:54
User entered 'Yes (Y)'		25 Sep 2020 16:48:50

US3272078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:54
User entered '25 Sep 2020'		25 Sep 2020 16:48:50

US3272078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:54
User entered 'Contact Made (CONTACT MADE)'		25 Sep 2020 16:48:50

US3272078

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:54
User entered empty.		25 Sep 2020 16:48:50

US3272078

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:08:59
User entered 'Yes (Y)'		25 Sep 2020 16:48:54

US3272078

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:34
User entered 'I'	System	25 Sep 2020 16:48:54

US3272078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:28
User entered 'Yes (Y)'		01 Oct 2020 16:28:26

US3272078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:28
User entered '01 Oct 2020'		01 Oct 2020 16:28:26

US3272078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:28
User entered 'Clinic (Clinic)'		01 Oct 2020 16:28:26

US3272078

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered 'VISIT3'	System	01 Oct 2020 16:28:26

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered 'Yes (Y)'		01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '01 Oct 2020'		01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '10:55'	(b) (4), (b) (6)	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered '01 Oct 2020 10:55'	System	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '36.8' C	(b) (4), (b) (6)	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '60'	(b) (4), (b) (6)	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered 'bpm'	System	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '14'		01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered 'breaths/min'	System	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '113'		01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered 'mmHg'	System	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:27:07
User entered '73'		01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered 'mmHg'	System	01 Oct 2020 16:29:21

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15

US3272078

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15

US3272078

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:38
User entered 'Yes (Y)'		01 Oct 2020 16:29:32

US3272078

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:38
User entered '01 Oct 2020'		01 Oct 2020 16:29:32

US3272078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:45
User entered 'Yes (Y)'		01 Oct 2020 16:29:48

US3272078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:45
User entered '01 Oct 2020'		01 Oct 2020 16:29:48

US3272078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:45
User entered '10:58'	(b) (4), (b) (6)	01 Oct 2020 16:29:48

US3272078

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered '01 Oct 2020 10:58'	System	01 Oct 2020 16:29:48

US3272078

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:29:52

US3272078

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:15
User entered 'I'	System	01 Oct 2020 16:29:52

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 64'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-07T13:00:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '2241aa3d-8fb8-4349-b23b-d34c0a82c1ba' User entered 'No (N)'	System	07 Oct 2020 18:00:29
	System	07 Oct 2020 18:00:29

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-07T13:00:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '2241aa3d-8fb8-4349-b23b-d34c0a82c1ba' User entered 'No (N)'	System	07 Oct 2020 18:00:29
	System	07 Oct 2020 18:00:29

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-07T13:00:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '2241aa3d-8fb8-4349-b23b-d34c0a82c1ba' User entered '07 Oct 2020 13:00:25'	System	07 Oct 2020 18:00:29
	System	07 Oct 2020 18:00:29

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 71'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-16T11:04:30', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'afdd0e87-a9d9-4222-b0e4-5bf5d2dc0fa2'	System	16 Oct 2020 16:04:42
User entered 'No (N)'	System	16 Oct 2020 16:04:42

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-16T11:04:35', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'afdd0e87-a9d9-4222-b0e4-5bf5d2dc0fa2'	System	16 Oct 2020 16:04:42
User entered 'No (N)'	System	16 Oct 2020 16:04:42

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-16T11:04:38', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'afdd0e87-a9d9-4222-b0e4-5bf5d2dc0fa2' User entered '16 Oct 2020 11:04:38'	System	16 Oct 2020 16:04:42
	System	16 Oct 2020 16:04:42

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 78'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-22T15:36:44', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e9756bf3-8ae6-4c15-ba87-fc07544ff615'	System	22 Oct 2020 20:36:51
User entered 'No (N)'	System	22 Oct 2020 20:36:51

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-22T15:36:46', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e9756bf3-8ae6-4c15-ba87-fc07544ff615'	System	22 Oct 2020 20:36:51
User entered 'No (N)'	System	22 Oct 2020 20:36:51

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-10-22T15:36:49', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e9756bf3-8ae6-4c15-ba87-fc07544ff615' User entered '22 Oct 2020 15:36:49'	System	22 Oct 2020 20:36:51
	System	22 Oct 2020 20:36:51

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 92'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-05T10:53:56', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e5bd6200-214c-4c79-8e98-3084ef6ffe69'	System	05 Nov 2020 16:54:03
User entered 'No (N)'	System	05 Nov 2020 16:54:03

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-05T10:53:59', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e5bd6200-214c-4c79-8e98-3084ef6ffe69'	System	05 Nov 2020 16:54:03
User entered 'No (N)'	System	05 Nov 2020 16:54:03

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-05T10:54:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e5bd6200-214c-4c79-8e98-3084ef6ffe69' User entered '05 Nov 2020 10:54:01'	System	05 Nov 2020 16:54:03
	System	05 Nov 2020 16:54:03

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 99'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-13T12:01:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '59c7dad5-8bd8-4348-9f8b-8a10bdc92eae' User entered 'No (N)'	System	13 Nov 2020 18:01:11
	System	13 Nov 2020 18:01:11

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-13T12:01:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '59c7dad5-8bd8-4348-9f8b-8a10bdc92eae' User entered 'No (N)'	System	13 Nov 2020 18:01:11
	System	13 Nov 2020 18:01:11

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-13T12:01:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '59c7dad5-8bd8-4348-9f8b-8a10bdc92eae' User entered '13 Nov 2020 12:01:06'	System	13 Nov 2020 18:01:11
	System	13 Nov 2020 18:01:11

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered 'Day 106'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-18T15:56:58', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '64681537-c9d9-4c50-8e7a-1475d083e68a'	System	18 Nov 2020 21:57:39
User entered 'Yes (Y)'	System	18 Nov 2020 21:57:39

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-18T15:57:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '64681537-c9d9-4c50-8e7a-1475d083e68a' User entered 'Yes (Y)'	System	18 Nov 2020 21:57:39
	System	18 Nov 2020 21:57:39

US3272078

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-18T15:57:13', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '64681537-c9d9-4c50-8e7a-1475d083e68a'	System	18 Nov 2020 21:57:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 21:57:39

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-18T15:57:19', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '64681537-c9d9-4c50-8e7a-1475d083e68a' User entered 'No (N)'	System	18 Nov 2020 21:57:39
	System	18 Nov 2020 21:57:39

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-18T15:57:23', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '64681537-c9d9-4c50-8e7a-1475d083e68a' User entered 'No (N)'	System	18 Nov 2020 21:57:39
	System	18 Nov 2020 21:57:39

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-11-18T15:57:28', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '64681537-c9d9-4c50-8e7a-1475d083e68a' User entered '18 Nov 2020 15:57:28'	System	18 Nov 2020 21:57:39
	System	18 Nov 2020 21:57:39

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 16:41:07

US3272078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:40:56
Data entry locked.	System	07 Aug 2020 16:41:07
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 16:41:07

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-01T12:05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6ba8b385-8a71-4736-a673-0c35e32fa268'	System	01 Dec 2020 18:05:17
User entered 'No (N)'	System	01 Dec 2020 18:05:17

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-01T12:05:04', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6ba8b385-8a71-4736-a673-0c35e32fa268'	System	01 Dec 2020 18:05:17
User entered 'Yes (Y)'	System	01 Dec 2020 18:05:17

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-01T12:05:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6ba8b385-8a71-4736-a673-0c35e32fa268'	System	01 Dec 2020 18:05:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Dec 2020 18:05:17

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-01T12:05:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '6ba8b385-8a71-4736-a673-0c35e32fa268' User entered '01 Dec 2020 12:05:09'	System	01 Dec 2020 18:05:17
	System	01 Dec 2020 18:05:17

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-06T00:02:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3b96ddd8-2775-4dd8-aff6-67ef9b327da3'	System	06 Dec 2020 06:02:56
User entered 'No (N)'	System	06 Dec 2020 06:02:56

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-06T00:02:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3b96ddd8-2775-4dd8-aff6-67ef9b327da3' User entered 'Yes (Y)'	System	06 Dec 2020 06:02:56
	System	06 Dec 2020 06:02:56

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-06T00:02:26', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3b96ddd8-2775-4dd8-aff6-67ef9b327da3'	System	06 Dec 2020 06:02:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 06:02:56

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-06T00:02:29', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3b96ddd8-2775-4dd8-aff6-67ef9b327da3' User entered '06 Dec 2020 00:02:29'	System	06 Dec 2020 06:02:56
	System	06 Dec 2020 06:02:56

US3272078

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	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-15T14:03:02', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a674f8fc-ffbb-439e-83f6-3a3621c08a6b' User entered 'No (N)'	System	15 Dec 2020 20:03:16
	System	15 Dec 2020 20:03:16

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-15T14:03:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a674f8fc-ffbb-439e-83f6-3a3621c08a6b' User entered 'No (N)'	System	15 Dec 2020 20:03:16

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-15T14:03:09', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'a674f8fc-ffbb-439e-83f6-3a3621c08a6b' User entered '15 Dec 2020 14:03:09'	System	15 Dec 2020 20:03:16
	System	15 Dec 2020 20:03:16

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-23T13:16:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'df3c028b-5991-4b8a-8291-17396d66b880'	System	23 Dec 2020 19:16:31
User entered 'No (N)'	System	23 Dec 2020 19:16:31

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-23T13:16:25', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'df3c028b-5991-4b8a-8291-17396d66b880'	System	23 Dec 2020 19:16:31
User entered 'No (N)'	System	23 Dec 2020 19:16:31

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-23T13:16:27', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'df3c028b-5991-4b8a-8291-17396d66b880' User entered '23 Dec 2020 13:16:27'	System	23 Dec 2020 19:16:31
	System	23 Dec 2020 19:16:31

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-27T00:10:12', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42905ded-9781-40fd-88b1-9b8e35c1ad89' User entered 'No (N)'	System	27 Dec 2020 06:10:20
	System	27 Dec 2020 06:10:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-27T00:10:15', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42905ded-9781-40fd-88b1-9b8e35c1ad89' User entered 'No (N)'	System	27 Dec 2020 06:10:20
	System	27 Dec 2020 06:10:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2058AF6D-9148-4F22-A5DF-FC8995DE50E3)', Time: '2020-12-27T00:10:18', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '42905ded-9781-40fd-88b1-9b8e35c1ad89' User entered '27 Dec 2020 00:10:18'	System	27 Dec 2020 06:10:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:48:19

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:48:19

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-01-17T11:45:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e999864d-c64f-425c-8f3d-108ae35e872f' User entered 'No (N)'	System	17 Jan 2021 17:45:22
	System	17 Jan 2021 17:45:22

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-01-17T11:45:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e999864d-c64f-425c-8f3d-108ae35e872f' User entered 'No (N)'	System	17 Jan 2021 17:45:22

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-01-17T11:45:20', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e999864d-c64f-425c-8f3d-108ae35e872f' User entered '17 Jan 2021 11:45:20'	System	17 Jan 2021 17:45:22
	System	17 Jan 2021 17:45:22

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-01-24T08:17:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3953d0ee-629c-4240-95b4-46387edd18a2' User entered 'No (N)'	System	24 Jan 2021 14:17:12
	System	24 Jan 2021 14:17:12

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-01-24T08:17:05', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3953d0ee-629c-4240-95b4-46387edd18a2'	System	24 Jan 2021 14:17:12
User entered 'No (N)'	System	24 Jan 2021 14:17:12

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-01-24T08:17:07', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '3953d0ee-629c-4240-95b4-46387edd18a2' User entered '24 Jan 2021 08:17:07'	System	24 Jan 2021 14:17:12
	System	24 Jan 2021 14:17:12

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-02T12:00:14', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5f3bc911-c007-4bcb-aa61-16e2814b3423' User entered 'No (N)'	System	02 Feb 2021 18:00:28
	System	02 Feb 2021 18:00:28

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-02T12:00:16', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5f3bc911-c007-4bcb-aa61-16e2814b3423'	System	02 Feb 2021 18:00:28
User entered 'No (N)'	System	02 Feb 2021 18:00:28

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-02T12:00:19', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '5f3bc911-c007-4bcb-aa61-16e2814b3423' User entered '02 Feb 2021 12:00:19'	System	02 Feb 2021 18:00:28
	System	02 Feb 2021 18:00:28

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-09T12:51:01', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '2755c4ad-cea1-4769-bd79-b3e97c388f0a' User entered 'No (N)'	System	09 Feb 2021 18:51:10
	System	09 Feb 2021 18:51:10

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-09T12:51:03', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '2755c4ad-cea1-4769-bd79-b3e97c388f0a' User entered 'No (N)'	System	09 Feb 2021 18:51:10
	System	09 Feb 2021 18:51:10

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-09T12:51:06', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '2755c4ad-cea1-4769-bd79-b3e97c388f0a' User entered '09 Feb 2021 12:51:06'	System	09 Feb 2021 18:51:10
	System	09 Feb 2021 18:51:10

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-14T21:29:36', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0184e2ca-b8f8-4a3b-84e1-5386d94c5a6a' User entered 'No (N)'	System	15 Feb 2021 03:29:46

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-14T21:29:40', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0184e2ca-b8f8-4a3b-84e1-5386d94c5a6a' User entered 'No (N)'	System	15 Feb 2021 03:29:46
	System	15 Feb 2021 03:29:46

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-14T21:29:43', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '0184e2ca-b8f8-4a3b-84e1-5386d94c5a6a' User entered '14 Feb 2021 21:29:43'	System	15 Feb 2021 03:29:46
	System	15 Feb 2021 03:29:46

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-22T14:35:17', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e508b5e7-7faa-483e-911c-2e7eb6ad03d5' User entered 'No (N)'	System	22 Feb 2021 20:35:25
	System	22 Feb 2021 20:35:25

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-22T14:35:19', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e508b5e7-7faa-483e-911c-2e7eb6ad03d5'	System	22 Feb 2021 20:35:25
User entered 'No (N)'	System	22 Feb 2021 20:35:25

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-22T14:35:22', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e508b5e7-7faa-483e-911c-2e7eb6ad03d5' User entered '22 Feb 2021 14:35:22'	System	22 Feb 2021 20:35:25
	System	22 Feb 2021 20:35:25

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-02T12:02:21-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '4b8e6bcf-6fff-4f50-b643-3e7be578c7d6'	System	02 Mar 2021 18:06:58
User entered 'No (N)'	System	02 Mar 2021 18:06:58

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-02T12:02:22-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '4b8e6bcf-6fff-4f50-b643-3e7be578c7d6'	System	02 Mar 2021 18:06:58
User entered 'No (N)'	System	02 Mar 2021 18:06:58

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-02T12:02:24-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '4b8e6bcf-6fff-4f50-b643-3e7be578c7d6'	System	02 Mar 2021 18:06:58
User entered '02 Mar 2021 12:02:24'	System	02 Mar 2021 18:06:58

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-07T16:11:29-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e2e96e10-7cad-408c-b097-5dacea598c8e' User entered 'No (N)'	System	16 Mar 2021 17:32:16
	System	16 Mar 2021 17:32:16

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-07T16:11:30-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e2e96e10-7cad-408c-b097-5dacea598c8e' User entered 'No (N)'	System	16 Mar 2021 17:32:16

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-07T16:11:33-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e2e96e10-7cad-408c-b097-5dacea598c8e' User entered '07 Mar 2021 16:11:33'	System	16 Mar 2021 17:32:16
	System	16 Mar 2021 17:32:16

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-16T12:32:12-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '39b71afa-03ab-4e39-9457-d7f16d9a57f0' User entered 'No (N)'	System	16 Mar 2021 17:32:19
	System	16 Mar 2021 17:32:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-16T12:32:14-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '39b71afa-03ab-4e39-9457-d7f16d9a57f0'	System	16 Mar 2021 17:32:19
User entered 'No (N)'	System	16 Mar 2021 17:32:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-16T12:32:17-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '39b71afa-03ab-4e39-9457-d7f16d9a57f0' User entered '16 Mar 2021 12:32:17'	System	16 Mar 2021 17:32:19
	System	16 Mar 2021 17:32:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-21T00:48:46-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7fa8be13-048e-4c4c-a42f-523ede7369e3'	System	21 Mar 2021 05:49:20
User entered 'No (N)'	System	21 Mar 2021 05:49:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-21T00:48:47-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7fa8be13-048e-4c4c-a42f-523ede7369e3'	System	21 Mar 2021 05:49:20
User entered 'No (N)'	System	21 Mar 2021 05:49:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-21T00:48:50-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '7fa8be13-048e-4c4c-a42f-523ede7369e3'	System	21 Mar 2021 05:49:20
User entered '21 Mar 2021 00:48:50'	System	21 Mar 2021 05:49:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-28T13:56:43-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b19f2b39-fe57-41b6-bc76-d1376a980a77'	System	28 Mar 2021 18:57:00
User entered 'Yes (Y)'	System	28 Mar 2021 18:57:00

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-28T13:56:45-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b19f2b39-fe57-41b6-bc76-d1376a980a77'	System	28 Mar 2021 18:57:00
User entered 'No (N)'	System	28 Mar 2021 18:57:00

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[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 (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-28T13:56:48-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b19f2b39-fe57-41b6-bc76-d1376a980a77'	System	28 Mar 2021 18:57:00
User entered 'No (N)'	System	28 Mar 2021 18:57:00

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[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 (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-28T13:56:53-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b19f2b39-fe57-41b6-bc76-d1376a980a77'	System	28 Mar 2021 18:57:00
User entered 'No (N)'	System	28 Mar 2021 18:57:00

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-03-28T13:56:56-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'b19f2b39-fe57-41b6-bc76-d1376a980a77'	System	28 Mar 2021 18:57:00
User entered '28 Mar 2021 13:56:56'	System	28 Mar 2021 18:57:00

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-04T10:12:48-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'aba37fcf-abb0-44f2-a46e-1a66df09cb91' User entered 'Yes (Y)'	System	04 Apr 2021 15:13:20
	System	04 Apr 2021 15:13:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-04T10:12:50-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'aba37fcf-abb0-44f2-a46e-1a66df09cb91'	System	04 Apr 2021 15:13:20
User entered 'No (N)'	System	04 Apr 2021 15:13:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[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 (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-04T10:12:53-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'aba37fcf-abb0-44f2-a46e-1a66df09cb91'	System	04 Apr 2021 15:13:20
User entered 'No (N)'	System	04 Apr 2021 15:13:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[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 (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-04T10:13:01-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'aba37fcf-abb0-44f2-a46e-1a66df09cb91'	System	04 Apr 2021 15:13:20
User entered 'Yes (Y)'	System	04 Apr 2021 15:13:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-04T10:13:06-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'aba37fcf-abb0-44f2-a46e-1a66df09cb91'	System	04 Apr 2021 15:13:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Apr 2021 15:13:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-04T10:13:08-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'aba37fcf-abb0-44f2-a46e-1a66df09cb91'	System	04 Apr 2021 15:13:20
User entered '04 Apr 2021 10:13:08'	System	04 Apr 2021 15:13:20

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-14T17:59:13-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '977cf4f3-325f-4e87-ae96-22c62b2f797d' User entered 'No (N)'	System	14 Apr 2021 22:59:21
	System	14 Apr 2021 22:59:21

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-14T17:59:16-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '977cf4f3-325f-4e87-ae96-22c62b2f797d' User entered 'No (N)'	System	14 Apr 2021 22:59:21
	System	14 Apr 2021 22:59:21

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-14T17:59:18-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '977cf4f3-325f-4e87-ae96-22c62b2f797d' User entered '14 Apr 2021 17:59:18'	System	14 Apr 2021 22:59:21
	System	14 Apr 2021 22:59:21

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-18T09:31:58-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '1c05c759-4259-446d-b309-274bd5d4ae1d' User entered 'No (N)'	System	18 Apr 2021 14:32:04
	System	18 Apr 2021 14:32:04

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-18T09:32:00-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '1c05c759-4259-446d-b309-274bd5d4ae1d'	System	18 Apr 2021 14:32:04
User entered 'No (N)'	System	18 Apr 2021 14:32:04

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-18T09:32:02-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '1c05c759-4259-446d-b309-274bd5d4ae1d'	System	18 Apr 2021 14:32:04
User entered '18 Apr 2021 09:32:02'	System	18 Apr 2021 14:32:04

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-25T17:18:25-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e8c19022-9719-4bb0-ba0c-fcb14cc82ef9'	System	25 Apr 2021 22:18:32
User entered 'No (N)'	System	25 Apr 2021 22:18:32

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-25T17:18:27-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e8c19022-9719-4bb0-ba0c-fcb14cc82ef9'	System	25 Apr 2021 22:18:32
User entered 'No (N)'	System	25 Apr 2021 22:18:32

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-04-25T17:18:29-05:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: 'e8c19022-9719-4bb0-ba0c-fcb14cc82ef9'	System	25 Apr 2021 22:18:32
User entered '25 Apr 2021 17:18:29'	System	25 Apr 2021 22:18:32

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:48:19

US3272078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:19
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:48:19

US3272078

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-27T20:36:29-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '08faafe5-9b16-4501-9592-526d887736d0'	System	28 Feb 2021 02:36:48
User entered 'Yes (Y)'	System	28 Feb 2021 02:36:48

US3272078

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:48

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-27T20:36:33-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '08faafe5-9b16-4501-9592-526d887736d0' User entered 'No (N)'	System	28 Feb 2021 02:36:48
	System	28 Feb 2021 02:36:48

US3272078

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8B59FDF7-C058-4544-9952-0DC0369745EA)', Time: '2021-02-27T20:36:37-06:00', User OID: 'PatientReportedOutcome (US3272078)', ODM File OID: '08faafe5-9b16-4501-9592-526d887736d0' User entered '28 Feb 2021 02:36:37'	System	28 Feb 2021 02:36:48
	System	28 Feb 2021 02:36:48

US3272078

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:15:53

US3272078

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:05:43
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:15:53

US3272078

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:05:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 14:15:53

US3272078

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:05:43
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:15:53

US3272078

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:15:58

US3272078

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:05
User entered 'I'	System	27 Oct 2020 14:15:58

US3272078

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:23:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 21:12:07

US3272078

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:23:21
User entered '01 Dec 2020'	(b) (4), (b) (6)	01 Dec 2020 21:12:07

US3272078

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:23:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Dec 2020 21:12:07

US3272078

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:23:21
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 21:12:07

US3272078

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:23:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 21:12:14

US3272078

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:37
User entered 'I'	System	01 Dec 2020 21:12:14

US3272078

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:20:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 15:51:22

US3272078

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:20:08
User entered '30 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 15:51:22

US3272078

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:20:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Dec 2020 15:51:22

US3272078

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:20:08
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 15:51:22

US3272078

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:24:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 15:51:26

US3272078

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:57
User entered 'I'	System	30 Dec 2020 15:51:26

US3272078

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:21:21
User entered 'Yes (Y)'		02 Feb 2021 21:39:24

US3272078

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:21:21
User entered '29 Jan 2021'		02 Feb 2021 21:39:24

US3272078

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:21:21
User entered 'Contact Made (CONTACT MADE)'		02 Feb 2021 21:39:24

US3272078

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:21:21
User entered empty.		02 Feb 2021 21:39:24

US3272078

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:23:24
User entered 'Yes (Y)'		02 Feb 2021 21:39:29

US3272078

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:49
User entered 'I'	System	02 Feb 2021 21:39:29

US3272078

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:24
User entered 'Yes (Y)'		17 Mar 2021 22:50:18

US3272078

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:24
User entered '15 Mar 2021'		17 Mar 2021 22:50:18

US3272078

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:24
User entered 'Clinic (Clinic)'		17 Mar 2021 22:50:18

US3272078

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered 'VISIT4'	System	17 Mar 2021 22:50:18

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered 'No (N)'	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered empty.	System	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered empty.	System	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered empty.	System	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered empty.	System	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:30
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered empty.	System	30 Mar 2021 23:49:05

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58

US3272078

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58

US3272078

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:49
User entered 'Yes (Y)'		17 Mar 2021 22:50:27

US3272078

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:18:49
User entered '15 Mar 2021'		17 Mar 2021 22:50:27

US3272078

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:19:07
User entered 'Yes (Y)'		17 Mar 2021 22:51:14

US3272078

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:19:07
User entered '15 Mar 2021'		17 Mar 2021 22:51:14

US3272078

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:19:07
User entered '10:30'		17 Mar 2021 22:51:14

US3272078

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered '15 Mar 2021 10:30'	System	17 Mar 2021 22:51:14

US3272078

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:13:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 22:51:17

US3272078

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:58
User entered 'I'	System	17 Mar 2021 22:51:17

US3272078

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:49:27

US3272078

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Apr 2021 18:49:27

US3272078

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Apr 2021 18:49:27

US3272078

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:49:27

US3272078

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:49:32

US3272078

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:49:32

US3272078

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:49:45

US3272078

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered '29 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 18:49:45

US3272078

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Apr 2021 18:49:45

US3272078

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:49:45

US3272078

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:49:49

US3272078

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:49:49

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:29
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 15JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:49:39
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 15JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' answered with 'data has already been recorded under immunogenicity assessment' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 21:42:14
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 15JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:14:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 20:27:09

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:29
User entered '15 Jan 2021'		15 Jan 2021 20:27:09

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:29
User entered 'Clinic (Clinic)'		15 Jan 2021 20:27:09

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 20:27:09

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered '15 Jan 2021'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:52:13

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered 'Yes (Y)'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:52:13

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered '15 Jan 2021'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered 'mRNA-1273 (mRNA-1273)'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered 'mRNA-1273 (mRNA-1273)'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered 'mRNA-1273 (mRNA-1273)'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:37
User entered 'No (N)'		11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User entered empty.	System	11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:24:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User entered empty.	System	11 Feb 2021 23:05:31

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:55
User entered 'Yes (Y)'		11 Feb 2021 23:08:12

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:55
User entered '15 Jan 2021'		11 Feb 2021 23:08:12

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:55
User entered '13:43'		11 Feb 2021 23:08:12

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User entered '15 Jan 2021 13:43'	System	11 Feb 2021 23:08:12

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:10:13
User entered 'Yes (Y)'		11 Feb 2021 23:08:54

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:48

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:10:13
User entered '15 Jan 2021'		11 Feb 2021 23:08:54

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:10:13
User entered '13:46'		11 Feb 2021 23:08:54

US3272078

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:48

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:45
User entered '15 Jan 2021 13:46'	System	11 Feb 2021 23:08:54

US3272078

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:24:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:39
DataPoint Verified.	(b) (4)	23 Apr 2021 14:01:28
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
DataPoint Un-verified.	Whitney West (b) (4)	09 Apr 2021 21:54:40
Signature has been broken.	(b) (4) Whitney West (b) (4)	09 Apr 2021 21:54:40
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	09 Apr 2021 21:54:40
User signature succeeded.	(b) (4) Adam Brosz (b) (4)	09 Apr 2021 14:53:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 17:13:14
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 18:15:04

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:11
User entered 'USA-US070-2021-mRNA-1273-P301000008'	System	12 Apr 2021 17:34:06
User entered 'New'	(b) (4), (b) (6)	12 Apr 2021 17:34:06

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural haematoma, LLT: Postoperative hematoma - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 11:34:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
Data point term sent to Coder	System	12 Apr 2021 15:52:33
Coding entries removed.	Whitney West (b) (4)	12 Apr 2021 15:52:30
User entered 'POSTOPERATIVE HEMATOMA OF BREAST, left' reason for change: New Information	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural haematoma, LLT: Postoperative hematoma - version MedDRA\23.0.	Whitney West (b) (4)	12 Apr 2021 15:52:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:26:49
Data point term sent to Coder	(b) (4)	
User entered 'Postoperative hematoma of breast'	Coder Import (b) (4)	11 Apr 2021 19:26:49
	(b) (4)	
	System	09 Apr 2021 22:03:11
	Whitney West (b) (4)	09 Apr 2021 22:02:31
	(b) (4)	

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'No (N)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'No (N)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '25 Mar 2021'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'No (N)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '28 Mar 2021'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'I'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'I'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:24:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '25 Mar 2021'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '28 Mar 2021'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'No (N)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'I'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'I'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.	(b) (4), (b) (6)	03 May 2021 16:38:14
' (Site from Safety). User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		03 May 2021 16:38:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'waiting on medical records will update when we receive them. ' (Site from Safety).		30 Apr 2021 19:55:41
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.	Whitney West (b) (4) (b) (4)	30 Apr 2021 14:40:44
' answered with 'Awaiting response to medical record request. ' (Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 04:04:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		27 Apr 2021 04:04:19
DataPoint Verified.		26 Apr 2021 20:12:18
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		20 Apr 2021 17:43:35
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		20 Apr 2021 17:43:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		20 Apr 2021 17:43:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Have requested records. No results currently available. Will update as available. ' (Site from Safety).	Whitney West (b) (4)	19 Apr 2021 20:50:08
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No COVID-19 testing. ' (Site from Safety).	Whitney West (b) (4)	19 Apr 2021 20:49:52
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Have requested records. No results currently available. Will update as available. ' (Site from Safety).	Whitney West (b) (4)	19 Apr 2021 20:49:30
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 15:36:16
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 15:36:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 15:36:00
	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'SUBJECT HAD OUTPATIENT BREAST REDUCTION 25MAR2021. DEVELOPED POSTOPERATIVE HEMATOMA of left breast, BLOOD LOSS 700-800 CC. FOLLOW UP SURGICAL EVACUATION and inpatient admission. 2 units PRBC transfused 25MAR2021 and 2 units PRBC 27MAR2021. Dismissed 27MAR2021. Does not recall medications given. Request for records sent to hospital and two clinics for follow-up visits. Awaiting response.' reason for change: New Information	Whitney West (b) (4)	12 Apr 2021 15:52:30
User entered 'Subject had outpatient breast reduction 25MAR2021. Developed postoperative hematoma, blood loss 700-800 cc. Follow up surgical evacuation, 4 units blood transfused during 2-day hospital stay. Requesting more information, subject to call back.'	Whitney West (b) (4)	09 Apr 2021 22:02:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 22:02:31

US3272078

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 22:02:31

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:24:48

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:54
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 13:22:17
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'data updated in con meds' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 21:25:54
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:18:44
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:54:57

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:24:48

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	(b) (4), (b) (6)	11 Feb 2021 23:02:45
answered with 'ibuprofen was taken as recorded on line 3 on con. med log' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		03 Feb 2021 06:12:10
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 16:26:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:43:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:43:56
Data point term sent to Coder	System	30 Oct 2020 16:28:12
User entered 'Lexapro'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'No (N)'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Anxiety'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '10'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'mg (mg)'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'once daily (QD)'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Oral (ORAL)'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'un UNK 2017'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '0'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Yes (Y)'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'No (N)'	Kayla Flege (b) (4)	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 16:27:36

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 21:50:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 21:50:39
Data point term sent to Coder	System	01 Dec 2020 22:53:04
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	01 Dec 2020 22:53:03
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'updated' (Site from System).	Kayla Flege (b) (4)	01 Dec 2020 22:53:03
User entered 'BIOIDENTICAL HORMONE (testosterone)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 22:52:59
Data point term sent to Coder	System	30 Nov 2020 22:17:29
User entered 'BIOIDENTICAL HORMONE' reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Nov 2020 22:16:30
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 14:04:09
Data point term sent to Coder	System	30 Oct 2020 16:30:16
User entered 'Bio Identical Hormone'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'No (N)'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'premenopausal'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '50' reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Dec 2020 22:24:51
User entered '1'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User closed query 'Per CDM: Response for Dose unit is recorded as "Injection", please provide the actual dose received by the subject. Kindly review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:36:02
Query 'Per CDM: Response for Dose unit is recorded as "Injection", please provide the actual dose received by the subject. Kindly review and update accordingly, else clarify.' answered with 'udpated' (Site from DM).	Kayla Flege (b) (4)	14 Dec 2020 22:24:55
User entered 'mg (mg)' reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Dec 2020 22:24:51
User opened query 'Per CDM: Response for Dose unit is recorded as "Injection", please provide the actual dose received by the subject. Kindly review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:44:37
User entered 'Other (OTHER)'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4)	14 Dec 2020 22:24:51
User entered 'Injection'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'other (OTHER)'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'every 3 days'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Intramuscular (INTRAMUSCULAR)'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'un Feb 2020'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '0'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Yes (Y)'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'No (N)'	Kayla Flege (b) (4)	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:29:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:32:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:32:07
Data point term sent to Coder	System	30 Oct 2020 16:31:17
User entered 'Ibuprofen'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User closed query 'Per DM CLR: Prophylaxis = YES, however, this medication is taken for a Solicited Adverse Event. Please review if the response in this field should be updated otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:25:41
Query 'Per DM CLR: Prophylaxis = YES, however, this medication is taken for a Solicited Adverse Event. Please review if the response in this field should be updated otherwise provide clarification.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	09 Dec 2020 20:52:07
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	09 Dec 2020 20:52:03
User opened query 'Per DM CLR: Prophylaxis = YES, however, this medication is taken for a Solicited Adverse Event. Please review if the response in this field should be updated otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 12:53:37
User entered 'Yes (Y)'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 11:36:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'this does not qualify as a med needed for an AE, as the condition lasted less than 24 hours.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:57:33

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 12:46:37
User closed query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:25:43
Query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' answered with 'headache noted on diary' (Site from DM).	Kayla Flege (b) (4)	09 Dec 2020 20:53:03
User opened query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 12:56:51
User entered 'Headache'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '200'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'mg (mg)'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'as needed (PRN)'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Oral (ORAL)'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '05 Sep 2020'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '0'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:39:52
User entered 'Yes (Y)'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered '05 Sep 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:39:52
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Nov 2020 23:39:52
User entered 'No (N)'	Kayla Flege (b) (4)	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:30:46

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 21:21:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 21:21:51
Data point term sent to Coder User entered 'Botox'	System (b) (4), (b) (6)	09 Apr 2021 21:20:30 09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Cosmetic injection'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Other (OTHER)'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'injection'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'other (OTHER)'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'every 3 month'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'un UNK 2018'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:10
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:20:22

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	03 May 2021 16:59:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 15:58:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 15:58:59
Data point term sent to Coder	System	30 Apr 2021 18:52:59
User entered 'Oxycodone'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Reduction mammoplasty'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'None'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Not specified'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'as needed (PRN)'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered '25 Mar 2021'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:13

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 17:02:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 17:02:09
Data point term sent to Coder	System	30 Apr 2021 18:52:59
User entered 'Ultram'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Reduction mammoplasty'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Not specified'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Not specified'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'as needed (PRN)'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered '25 Mar 2021'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:55

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:24:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:39
DataPoint Verified.	(b) (4)	26 Apr 2021 20:14:26
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
DataPoint Un-verified.	Whitney West (b) (4)	12 Apr 2021 15:52:43
Signature has been broken.	(b) (4) Whitney West (b) (4)	12 Apr 2021 15:52:43
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	12 Apr 2021 15:52:43
User signature succeeded.	(b) (4) Adam Brosz (b) (4)	09 Apr 2021 14:53:01
User closed query 'Per CDM: Please update medication used for dairy dose 2 day 1' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:18:43
Query 'Per CDM: Please update medication used for dairy dose 2 day 1' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	30 Oct 2020 16:35:16
User opened query 'Per CDM: Please update medication used for dairy dose 2 day 1' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:08:23
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:12:54
		10 Aug 2020 18:15:09

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:15:35
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '25 Mar 2021'	Whitney West (b) (4)	12 Apr 2021 15:53:57

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:15:37
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Reduction mammoplasty'	Whitney West (b) (4)	12 Apr 2021 15:53:57

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:15:38
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Medical History (MH)'	Whitney West (b) (4)	12 Apr 2021 15:53:57

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:48

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:15:41
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4)	12 Apr 2021 15:53:57

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:24:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:22
DataPoint Verified.		26 Apr 2021 20:17:11
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '25 Mar 2021'	Whitney West (b) (4)	12 Apr 2021 15:57:41

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:24:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:22
DataPoint Verified.		26 Apr 2021 20:17:26
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Evacuation of hematoma, left breast'	Whitney West (b) (4)	12 Apr 2021 15:57:41

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:22
DataPoint Verified.		26 Apr 2021 20:17:27
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	12 Apr 2021 15:57:41

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:24:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:17:30
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered empty.	Whitney West (b) (4) (b) (4)	12 Apr 2021 15:57:41

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:24:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:17:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered '25 Mar 2021'	Whitney West (b) (4) (b) (4)	12 Apr 2021 15:58:23

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:24:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:12
DataPoint Verified.		26 Apr 2021 20:17:36
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Liposuction'	Whitney West (b) (4)	12 Apr 2021 15:58:23

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:24:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:12
DataPoint Verified.		26 Apr 2021 20:17:38
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Other (OTHER)'	Whitney West (b) (4)	12 Apr 2021 15:58:23

US3272078

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:24:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:34:12
DataPoint Verified.		26 Apr 2021 20:17:40
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:01:59
User entered 'Cosmetic'	Whitney West (b) (4)	12 Apr 2021 15:58:23

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'USA-US070-2021-MRNA-1273-P301000008'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'Yes (Y)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'Yes (Y)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'Yes (Y)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'Adam'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'Brosz'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered '2444 W. Faidley Ave'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'Grand Island'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered 'NE'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:34:31
User entered '68803'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
User entered 'US'	System	12 Apr 2021 17:34:40

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 17:34:40

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'USA-US070-2021-MRNA-1273-P301000008'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'Yes (Y)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'Yes (Y)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'Yes (Y)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'No (N)'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'Adam'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'Brosz'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered '2444 W. Faidley Ave'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'Grand Island'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered 'NE'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
Reviewed for Safety.		12 Apr 2021 17:34:31
User entered '68803'	System	12 Apr 2021 17:34:06

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
User entered 'US'	System	12 Apr 2021 17:34:40

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 17:34:40

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
User entered '12/Apr/2021 17:34'	System	12 Apr 2021 17:34:40

US3272078

Folder: SAE USA-US070-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:12:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:12
User entered 'I'		12 Apr 2021 17:34:40