

US3572027 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:59:11

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US3572027

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

[Participant ID](#)

US3572027

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

US3572027

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Mar 2021 23:41:55

Generated On: 11 Aug 2021 22:59:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3572027

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Mar 2021 23:41:54

Generated On: 11 Aug 2021 22:59:11

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Mar 2021 23:41:54

Generated On: 11 Aug 2021 22:59:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Mar 2021 23:41:54

Generated On: 11 Aug 2021 22:59:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Mar 2021 23:41:55

Generated On: 11 Aug 2021 22:59:11

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Mar 2021 23:41:54

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Condition	ADHD
Start date (dd MMM yyyy)	UN JUN 2019
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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Mar 2021 23:41:54

Generated On: 11 Aug 2021 22:59:11

Condition	GERD
Start date (dd MMM yyyy)	UN SEP 2019
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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Mar 2021 23:41:55

Generated On: 11 Aug 2021 22:59:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 12:41
Height (xxx.x)	64 in
Weight (xxx.x)	142 lb
BMI (xxx.x)	24.42521 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Mar 2021 23:41:55

Generated On: 11 Aug 2021 22:59:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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) 20 Mar 2021 23:41:54

Generated On: 11 Aug 2021 22:59:11

Date of assessment (dd MMM yyyy) 19 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) 20 Mar 2021 23:41:55

Generated On: 11 Aug 2021 22:59:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	19 AUG 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Mar 2021 23:41:55

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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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Mar 2021 23:41:55

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
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) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 106002

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

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) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 12:41
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:32
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 AUG 2020

What was the treatment time? (00:00-23:59) 13:02 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 13:02

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) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	12:41 (24 HR)
Collection date and time (derived)	19 AUG 2020 12:41

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:06	19 AUG 2020 13:06
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 13:35

PC Open Date & Time

19 AUG 2020 13:22

PC Close Date & Time

19 AUG 2020 15:52

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

96.0 °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	19 AUG 2020 23:51
PC Open Date & Time	19 AUG 2020 16:47
PC Close Date & Time	20 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	20 AUG 2020 21:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 22:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 23:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 23 AUG 2020 23:59

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 25 AUG 2020 09:35

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 23:32

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 15:37

PC Open Date & Time

19 AUG 2020 13:22

PC Close Date & Time

19 AUG 2020 15:52

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 23:52

PC Open Date & Time

19 AUG 2020 16:47

PC Close Date & Time

20 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 21:48

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 3
Please record - PAIN AT INJECTION SITE.	None <input type="radio"/>
Please select one response below	Does not interfere with activity <input checked="" type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	Does not interfere with activity <input type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	21 AUG 2020 22:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	22 AUG 2020 23:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 23:59

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 09:36

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	25 AUG 2020 23:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 15:38
PC Open Date & Time	19 AUG 2020 13:22
PC Close Date & Time	19 AUG 2020 15:52

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 23:52
PC Open Date & Time	19 AUG 2020 16:47
PC Close Date & Time	20 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 21:51
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 22:05
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 23:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 23:59
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 09:36
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 23:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3572027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

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

US3572027

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:08:48

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:48

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:48

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

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)	23 SEP 2020
Time of assessment (00:00-23:59)	07:45 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 07:45
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

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)	23 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3572027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	23 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)	

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 SEP 2020

What was the treatment time? (00:00-23:59) 8:40 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 8:40

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

US3572027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

07:53 (24 HR)

Collection date and time (derived)

23 SEP 2020 07:53

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:20	23 SEP 2020 08:20
Nasopharyngeal Swab 2	No		

US3572027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 09:07

PC Open Date & Time

23 SEP 2020 09:00

PC Close Date & Time

23 SEP 2020 11:30

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

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	23 SEP 2020 22:41
PC Open Date & Time	23 SEP 2020 12:25
PC Close Date & Time	24 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	24 SEP 2020 21:34
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 09:43

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

27 SEP 2020 09:20

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 22:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 22:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 09:03

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 09:07

PC Open Date & Time

23 SEP 2020 09:00

PC Close Date & Time

23 SEP 2020 11:30

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 22:34

PC Open Date & Time

23 SEP 2020 12:25

PC Close Date & Time

24 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

24 SEP 2020 22:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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)**

3

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

26 SEP 2020 09:47

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	27 SEP 2020 09:20
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 22:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 22:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 09:03

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 09:08
PC Open Date & Time	23 SEP 2020 09:00
PC Close Date & Time	23 SEP 2020 11:30

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 22:34
PC Open Date & Time	23 SEP 2020 12:25
PC Close Date & Time	24 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:40
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 09:48
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 09:21
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 22:00
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 22:14
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 09:03
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3572027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments UNABLE TO REACH

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 09:00
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3572027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	09:57 (24 HR)
Collection date and time (derived)	26 OCT 2020 09:57

US3572027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:08:49

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	19 OCT 2020 00:02:28
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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 <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	29 OCT 2020 18:23:52
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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 <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 NOV 2020 11:06:55
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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 <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	16 NOV 2020 09:02:14
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	23 NOV 2020 06:48:53
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 09:55:49

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	29 JAN 2021 00:04:02
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 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	05 FEB 2021 18:48:49
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	12 FEB 2021 06:52:23
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 08:50:37

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	26 FEB 2021 18:04:04
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 18:50:26

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 09:09:05

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	19 MAR 2021 17:52:01
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 07:46:19

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 09:16:47

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 19:16:50

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:47:34

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 13:04:00

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 16:44:25

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3572027

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:59:11

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
No		01 MAR 2021 07:08:55

US3572027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 05:14:23

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 05:14:23

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 DEC 2020

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

Comments UNABLE TO REACH

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3572027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3572027

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3572027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3572027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:03:46

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:03:46

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:03:46

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572027

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572027

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572027

Folder: Covid-19 Assessment (4)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3572027

Folder: Covid-19 Assessment (4)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:59:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Date of Contact	3 SEP 2020
Time of Contact	14:20
Date and Time of Contact (derived)	3 SEP 2020 14:20
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Date of Contact	10 SEP 2020
Time of Contact	08:55
Date and Time of Contact (derived)	10 SEP 2020 08:55
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Date of Contact	26 AUG 2020
Time of Contact	15:45
Date and Time of Contact (derived)	26 AUG 2020 15:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

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

Visit date (dd MMM yyyy)	26 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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US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Date of updated informed consent (dd MMM yyyy) 26 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) 26 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 _____

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

26 JAN 2021 09:15

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	09:11
Collection Date and Time (derived)	26 JAN 2021 09:11

US3572027

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Mar 2021 03:28:33

Generated On: 11 Aug 2021 22:59:11

AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	09 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Mar 2021 03:28:33

Generated On: 11 Aug 2021 22:59:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 400

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 (1)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

	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)	19 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication ETHINYL ESTRADIOL AND
NORGESTINATE

Prophylaxis Yes ☐
No ☒

Indication ORAL CONTRACEPTION

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

	Intraocular	<input type="checkbox"/>
	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)		UN JAN 2019
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 04:45:25

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	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)		01 SEP 2019
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication VYVANS

Prophylaxis Yes ☐
No ☒

Indication ADHD

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 04:45:25

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	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)	01 JUN 2019	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration UNK

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 (5)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 SEP 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication ANTIDEPRESSANT

Dose per administration ORAL

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 (6)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

	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)	14 OCT 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Name of Medication KLONOPIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

	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)	9 NOV 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 04:45:25

Generated On: 11 Aug 2021 22:59:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3572027

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:59:11

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3572027 (Prod: Laguna Clinical Research Associates)

US3572027

Form: Participant Creation

Generated On: 11 Aug 2021 22:59:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'US3572027'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:24

US3572027

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:11

US3572027

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:25

US3572027

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:11

US3572027

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'SCRN'	System	19 Aug 2020 17:45:11

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:26

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '31'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'YEARS'	System	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '31'	System	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Female (F)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Alisha Lutat (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:45:52

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'Aug 2020'	System	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '2020'	System	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Amendment 2 (2)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:46:48

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:25

US3572027

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'l'	System	19 Aug 2020 17:47:03

US3572027

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:03

US3572027

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:59:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:16:31

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User coded data point as SOC: Psychiatric disorders, HLT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:17:44
Data point term sent to Coder	System	02 Sep 2020 19:17:03
User entered 'ADHD'	Alisha Lutat (b) (4)	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'UN Jun 2019'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'Jun 2019'	System	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '2019'	System	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	02 Sep 2020 19:17:01

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:19:48
Data point term sent to Coder	System	02 Sep 2020 19:19:09
User entered 'GERD'	Alisha Lutat (b) (4)	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'UN Sep 2019'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'Sep 2019'	System	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '2019'	System	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	02 Sep 2020 19:18:59

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	02 Sep 2020 19:21:24
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	02 Sep 2020 19:21:24
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	02 Sep 2020 19:21:24
User entered '19 Aug 2020' reason for change: Data Entry Error	Alisha Lutat (b) (4)	02 Sep 2020 19:21:24
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	02 Sep 2020 19:19:56
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	02 Sep 2020 19:19:56
User entered '23 Aug 2020'	Alisha Lutat (b) (4)	02 Sep 2020 19:19:56
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '12:41'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '19 Aug 2020 12:41'	System	02 Sep 2020 19:21:24
User entered '23 Aug 2020 12:41'	System	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '64' in	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56
DataPoint set to visible.	(b) (4) System	19 Aug 2020 17:47:03

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '142' lb	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56
DataPoint set to visible.	(b) (4) System	19 Aug 2020 17:47:03

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '24.42521'	System	02 Sep 2020 19:19:56
DataPoint set to visible.	System	19 Aug 2020 17:47:03

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'kg/m2'	System	02 Sep 2020 19:19:56
DataPoint set to visible.	System	19 Aug 2020 17:47:03

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'bpm'	System	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'breaths/min'	System	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'mmHg'	System	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:19:56

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'mmHg'	System	02 Sep 2020 19:19:56

US3572027

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21

US3572027

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:39

US3572027

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:39

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

US3572027

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:11

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:21:59

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:05

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:05

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Urine (URINE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:05

US3572027

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Negative (NEGATIVE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:05

US3572027

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User closed query ' Per CDM: Was FSH sample collected? is No however collection date and time provide. Please reconcile and update appropriately.' (Site from DM). Query '	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:23:57
Per CDM: Was FSH sample collected? is No however collection date and time provide. Please reconcile and update appropriately.' answered with 'FSH collection date and time removed' (Site from DM).	Brett Potthoff (b) (4) (b) (4)	15 Sep 2020 00:14:29
User opened query ' Per CDM: Was FSH sample collected? is No however collection date and time provide. Please reconcile and update appropriately.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) Alisha Lutat (b) (4) (b) (4)	09 Sep 2020 10:22:18 02 Sep 2020 19:23:05

US3572027

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty; reason for change Data Entry Error	(b) (4) Brett Potthoff (b) (4)	15 Sep 2020 00:14:18
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:23:05

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty; reason for change Data Entry Error	(b) (4) Brett Potthoff (b) (4)	15 Sep 2020 00:14:18
User entered '12:45'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:23:05

US3572027

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	15 Sep 2020 00:14:18
User entered '19 Aug 2020 12:45'	System	02 Sep 2020 19:23:05

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

[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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:11

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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:41:55
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:23:53

US3572027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:23

US3572027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:23

US3572027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:23

US3572027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'VISIT1'	System	19 Aug 2020 17:47:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:34

US3572027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:37:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:37:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:39:34
User entered '106002' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:39:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:54

US3572027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:54

US3572027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:54

US3572027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 17:47:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:29:00
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:33:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '12:41'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered '19 Aug 2020 12:41'	System	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '97.9' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 19:31:31
User entered 'Other (Other)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	02 Sep 2020 19:31:31
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 19:31:16
User entered 'Oral (Oral)'	Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '104'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'bpm'	System	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'breaths/min'	System	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '124'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'mmHg'	System	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '84'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'mmHg'	System	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '13:32'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered '19 Aug 2020 13:32'	System	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '98.1' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 19:31:56
User entered 'Other (Other)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	02 Sep 2020 19:31:56
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 19:31:16
User entered 'Oral (Oral)'	Alisha Lutat (b) (4)	02 Sep 2020 19:31:16
	(b) (4)	

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Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '87'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'bpm'	System	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'breaths/min'	System	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '113'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'mmHg'	System	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '69'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'mmHg'	System	02 Sep 2020 19:31:16

US3572027

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:05

US3572027

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:05

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 05:01:13
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'Corrected' (Site from DM).	Brett Potthoff (b) (4) (b) (4)	15 Sep 2020 00:32:39
User entered 'No (N)' reason for change: Data Entry Error	Brett Potthoff (b) (4) (b) (4)	15 Sep 2020 00:32:19
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:21:08
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered empty.	System	02 Sep 2020 19:32:18

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4)	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '13:02'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered '19 Aug 2020 13:02'	System	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'ONCE'	System	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 18:16:40

US3572027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:32:41

US3572027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:32:41

US3572027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '12:41'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:32:41

US3572027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered '19 Aug 2020 12:41'	System	02 Sep 2020 19:32:41

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '19 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '13:06'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered '19 Aug 2020 13:06'	System	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered empty.	System	02 Sep 2020 19:33:03

US3572027

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:33:11

US3572027

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'I'	System	02 Sep 2020 19:33:11

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T13:31:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a56c613b-5c8c-49bd-81d6-5a1f3ef91870'	System	19 Aug 2020 18:35:44
User entered 'Yes (Y)'	System	19 Aug 2020 18:35:44

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T13:35:32', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a56c613b-5c8c-49bd-81d6-5a1f3ef91870' User entered '98.1'	System	19 Aug 2020 18:35:44
	System	19 Aug 2020 18:35:44

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T13:35:36', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a56c613b-5c8c-49bd-81d6-5a1f3ef91870'	System	19 Aug 2020 18:35:44
User entered 'No (N)'	System	19 Aug 2020 18:35:44

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T13:35:40', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a56c613b-5c8c-49bd-81d6-5a1f3ef91870'	System	19 Aug 2020 18:35:44
User entered '19 Aug 2020 13:35'	System	19 Aug 2020 18:35:44

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 13:22'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 15:52'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:50:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '30b2ee20-457b-4063-82e1-cf792688474c' User entered 'Yes (Y)'	System	20 Aug 2020 04:51:05
	System	20 Aug 2020 04:51:05

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:50:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '30b2ee20-457b-4063-82e1-cf792688474c' User entered '96.0'	System	20 Aug 2020 04:51:05
	System	20 Aug 2020 04:51:05

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:50:56', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '30b2ee20-457b-4063-82e1-cf792688474c' User entered 'No (N)'	System	20 Aug 2020 04:51:05
	System	20 Aug 2020 04:51:05

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:51:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '30b2ee20-457b-4063-82e1-cf792688474c' User entered '19 Aug 2020 23:51'	System	20 Aug 2020 04:51:05
	System	20 Aug 2020 04:51:05

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 16:47'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 2'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:39:07', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3f0e35f5-8c1f-4fb2-a5ce-ce115ebdf5c7'	System	21 Aug 2020 02:39:41
User entered 'Yes (Y)'	System	21 Aug 2020 02:39:41

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:39:12', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3f0e35f5-8c1f-4fb2-a5ce-ce115ebdf5c7'	System	21 Aug 2020 02:39:41
User entered '96.8'	System	21 Aug 2020 02:39:41

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:39:18', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3f0e35f5-8c1f-4fb2-a5ce-ce115ebdf5c7'	System	21 Aug 2020 02:39:41
User entered 'Yes (Y)'	System	21 Aug 2020 02:39:41

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed that patient took 2 tabs of 200 mg ibuprofen at 0845 for pain at injection site ' (Site from System).	(b) (4)	29 Aug 2020 18:36:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jackie Ziegler (b) (4)	27 Aug 2020 00:10:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:39:25', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3f0e35f5-8c1f-4fb2-a5ce-ce115ebdf5c7'	(b) (4)	
User entered '1'	System	21 Aug 2020 02:39:41
	System	21 Aug 2020 02:39:41
	System	21 Aug 2020 02:39:41

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:39:25', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3f0e35f5-8c1f-4fb2-a5ce-ce115ebdf5c7'	System	21 Aug 2020 02:39:41
User entered '0'	System	21 Aug 2020 02:39:41

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:39:38', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3f0e35f5-8c1f-4fb2-a5ce-ce115ebdf5c7'	System	21 Aug 2020 02:39:41
User entered '20 Aug 2020 21:39'	System	21 Aug 2020 02:39:41

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 3'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:03:19', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd644ca86-7b1f-4ac8-9b98-b82d0763bbd8' User entered 'Yes (Y)'	System	22 Aug 2020 03:03:36
	System	22 Aug 2020 03:03:36

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:03:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd644ca86-7b1f-4ac8-9b98-b82d0763bbd8' User entered '97.7'	System	22 Aug 2020 03:03:36
	System	22 Aug 2020 03:03:36

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:03:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd644ca86-7b1f-4ac8-9b98-b82d0763bbd8'	System	22 Aug 2020 03:03:36
User entered 'No (N)'	System	22 Aug 2020 03:03:36

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:03:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd644ca86-7b1f-4ac8-9b98-b82d0763bbd8'	System	22 Aug 2020 03:03:36
User entered '21 Aug 2020 22:03'	System	22 Aug 2020 03:03:36

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 4'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:36:35', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8e829c4c-df31-4489-a7aa-70bd46945220'	System	23 Aug 2020 04:36:52
User entered 'Yes (Y)'	System	23 Aug 2020 04:36:52

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:36:42', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8e829c4c-df31-4489-a7aa-70bd46945220' User entered '97.1'	System	23 Aug 2020 04:36:52
	System	23 Aug 2020 04:36:52

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:36:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8e829c4c-df31-4489-a7aa-70bd46945220'	System	23 Aug 2020 04:36:52
User entered 'No (N)'	System	23 Aug 2020 04:36:52

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:36:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8e829c4c-df31-4489-a7aa-70bd46945220' User entered '22 Aug 2020 23:36'	System	23 Aug 2020 04:36:52
	System	23 Aug 2020 04:36:52

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 5'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:20', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '25c15107-ae30-44b2-9d7e-76225dd74c03'	System	24 Aug 2020 04:59:29
User entered 'No (N)'	System	24 Aug 2020 04:59:29

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:24', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '25c15107-ae30-44b2-9d7e-76225dd74c03'	System	24 Aug 2020 04:59:29
User entered 'No (N)'	System	24 Aug 2020 04:59:29

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '25c15107-ae30-44b2-9d7e-76225dd74c03'	System	24 Aug 2020 04:59:29
User entered '23 Aug 2020 23:59'	System	24 Aug 2020 04:59:29

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 6'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:35:47', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '25b981df-9910-4501-be5c-d005e1407874' User entered 'No (N)'	System	25 Aug 2020 14:35:56
	System	25 Aug 2020 14:35:56

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:35:49', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '25b981df-9910-4501-be5c-d005e1407874'	System	25 Aug 2020 14:35:56
User entered 'No (N)'	System	25 Aug 2020 14:35:56

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:35:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '25b981df-9910-4501-be5c-d005e1407874' User entered '25 Aug 2020 09:35'	System	25 Aug 2020 14:35:56
	System	25 Aug 2020 14:35:56

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 7'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:06', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df8d9dd8-cc1c-42d2-8983-c26dd8cb7af8'	System	26 Aug 2020 04:32:19
User entered 'Yes (Y)'	System	26 Aug 2020 04:32:19

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df8d9dd8-cc1c-42d2-8983-c26dd8cb7af8' User entered '97.2'	System	26 Aug 2020 04:32:19
	System	26 Aug 2020 04:32:19

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df8d9dd8-cc1c-42d2-8983-c26dd8cb7af8'	System	26 Aug 2020 04:32:19
User entered 'No (N)'	System	26 Aug 2020 04:32:19

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:18', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df8d9dd8-cc1c-42d2-8983-c26dd8cb7af8'	System	26 Aug 2020 04:32:19
User entered '25 Aug 2020 23:32'	System	26 Aug 2020 04:32:19

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T13:37:12', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8c35b2da-bc3b-4e3e-a58d-dadba4608b1b' User entered 'None (1)'	System	19 Aug 2020 20:37:39
	System	19 Aug 2020 20:37:39

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8c35b2da-bc3b-4e3e-a58d-dadba4608b1b' User entered 'No (N)'	System	19 Aug 2020 20:37:39
	System	19 Aug 2020 20:37:39

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:26', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8c35b2da-bc3b-4e3e-a58d-dadba4608b1b' User entered 'No (N)'	System	19 Aug 2020 20:37:39
	System	19 Aug 2020 20:37:39

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:30', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8c35b2da-bc3b-4e3e-a58d-dadba4608b1b' User entered 'None (1)'	System	19 Aug 2020 20:37:39
	System	19 Aug 2020 20:37:39

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8c35b2da-bc3b-4e3e-a58d-dadba4608b1b' User entered '19 Aug 2020 15:37'	System	19 Aug 2020 20:37:39
	System	19 Aug 2020 20:37:39

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 13:22'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 15:52'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:51:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '710daacb-f844-4b22-803f-6d14b7e8ecal'	System	20 Aug 2020 04:52:26
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 04:52:26

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:51:28', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '710daacb-f844-4b22-803f-6d14b7e8ecal'	System	20 Aug 2020 04:52:26
User entered 'No (N)'	System	20 Aug 2020 04:52:26

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '710daacb-f844-4b22-803f-6d14b7e8ecal'	System	20 Aug 2020 04:52:26
User entered 'No (N)'	System	20 Aug 2020 04:52:26

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:19', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '710daacb-f844-4b22-803f-6d14b7e8ecal'	System	20 Aug 2020 04:52:26
User entered 'None (1)'	System	20 Aug 2020 04:52:26

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:22', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '710daacb-f844-4b22-803f-6d14b7e8ecal'	System	20 Aug 2020 04:52:26
User entered '19 Aug 2020 23:52'	System	20 Aug 2020 04:52:26

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 16:47'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 2'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:46:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'fd2b44bb-2901-4760-a001-7311e07756bc'	System	21 Aug 2020 02:48:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Aug 2020 02:48:37

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:41:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'fd2b44bb-2901-4760-a001-7311e07756bc' User entered 'No (N)'	System	21 Aug 2020 02:48:37
	System	21 Aug 2020 02:48:37

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:41:43', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'fd2b44bb-2901-4760-a001-7311e07756bc' User entered 'No (N)'	System	21 Aug 2020 02:48:37
	System	21 Aug 2020 02:48:37

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:47:40', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'fd2b44bb-2901-4760-a001-7311e07756bc' User entered 'None (1)'	System	21 Aug 2020 02:48:37
	System	21 Aug 2020 02:48:37

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:48:33', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'fd2b44bb-2901-4760-a001-7311e07756bc' User entered '20 Aug 2020 21:48'	System	21 Aug 2020 02:48:37
	System	21 Aug 2020 02:48:37

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 3'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:04:08', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b86359af-2096-4f7e-a153-68ee75bd16a6'	System	22 Aug 2020 03:05:03
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 03:05:03

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:04:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b86359af-2096-4f7e-a153-68ee75bd16a6'	System	22 Aug 2020 03:05:03
User entered 'No (N)'	System	22 Aug 2020 03:05:03

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:04:15', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b86359af-2096-4f7e-a153-68ee75bd16a6'	System	22 Aug 2020 03:05:03
User entered 'No (N)'	System	22 Aug 2020 03:05:03

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:04:56', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b86359af-2096-4f7e-a153-68ee75bd16a6'	System	22 Aug 2020 03:05:03
User entered 'None (1)'	System	22 Aug 2020 03:05:03

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:04:59', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b86359af-2096-4f7e-a153-68ee75bd16a6' User entered '21 Aug 2020 22:04'	System	22 Aug 2020 03:05:03
	System	22 Aug 2020 03:05:03

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 4'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:36:54', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f65dc7ed-ff6f-4cd9-a44a-8d00d96f4960'	System	23 Aug 2020 04:37:07
User entered 'None (1)'	System	23 Aug 2020 04:37:07

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:36:57', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f65dc7ed-ff6f-4cd9-a44a-8d00d96f4960'	System	23 Aug 2020 04:37:07
User entered 'No (N)'	System	23 Aug 2020 04:37:07

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f65dc7ed-ff6f-4cd9-a44a-8d00d96f4960'	System	23 Aug 2020 04:37:07
User entered 'No (N)'	System	23 Aug 2020 04:37:07

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f65dc7ed-ff6f-4cd9-a44a-8d00d96f4960'	System	23 Aug 2020 04:37:07
User entered 'None (1)'	System	23 Aug 2020 04:37:07

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:05', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f65dc7ed-ff6f-4cd9-a44a-8d00d96f4960'	System	23 Aug 2020 04:37:07
User entered '22 Aug 2020 23:37'	System	23 Aug 2020 04:37:07

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 5'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:30', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '190dbd5d-26cd-4d99-bc76-d07297331251'	System	24 Aug 2020 04:59:44
User entered 'None (1)'	System	24 Aug 2020 04:59:44

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:33', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '190dbd5d-26cd-4d99-bc76-d07297331251'	System	24 Aug 2020 04:59:44
User entered 'No (N)'	System	24 Aug 2020 04:59:44

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:35', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '190dbd5d-26cd-4d99-bc76-d07297331251'	System	24 Aug 2020 04:59:44
User entered 'No (N)'	System	24 Aug 2020 04:59:44

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:39', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '190dbd5d-26cd-4d99-bc76-d07297331251'	System	24 Aug 2020 04:59:44
User entered 'None (1)'	System	24 Aug 2020 04:59:44

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '190dbd5d-26cd-4d99-bc76-d07297331251'	System	24 Aug 2020 04:59:44
User entered '23 Aug 2020 23:59'	System	24 Aug 2020 04:59:44

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 6'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:35:55', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0090324-e0b3-434b-ae98-633dea56a1b1'	System	25 Aug 2020 14:36:10
User entered 'None (1)'	System	25 Aug 2020 14:36:10

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:35:57', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0090324-e0b3-434b-ae98-633dea56a1b1' User entered 'No (N)'	System	25 Aug 2020 14:36:10
	System	25 Aug 2020 14:36:10

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:02', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0090324-e0b3-434b-ae98-633dea56a1b1'	System	25 Aug 2020 14:36:10
User entered 'No (N)'	System	25 Aug 2020 14:36:10

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0090324-e0b3-434b-ae98-633dea56a1b1'	System	25 Aug 2020 14:36:10
User entered 'None (1)'	System	25 Aug 2020 14:36:10

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:05', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0090324-e0b3-434b-ae98-633dea56a1b1'	System	25 Aug 2020 14:36:10
User entered '25 Aug 2020 09:36'	System	25 Aug 2020 14:36:10

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 7'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:22', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a220560e-bece-4925-ab88-77942e65204d' User entered 'None (1)'	System	26 Aug 2020 04:32:36
	System	26 Aug 2020 04:32:36

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a220560e-bece-4925-ab88-77942e65204d' User entered 'No (N)'	System	26 Aug 2020 04:32:36
	System	26 Aug 2020 04:32:36

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:29', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a220560e-bece-4925-ab88-77942e65204d' User entered 'No (N)'	System	26 Aug 2020 04:32:36
	System	26 Aug 2020 04:32:36

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:32', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a220560e-bece-4925-ab88-77942e65204d' User entered 'None (1)'	System	26 Aug 2020 04:32:36
	System	26 Aug 2020 04:32:36

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a220560e-bece-4925-ab88-77942e65204d' User entered '25 Aug 2020 23:32'	System	26 Aug 2020 04:32:36
	System	26 Aug 2020 04:32:36

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:43', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered 'None (0)'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered 'None (0)'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:55', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered 'None (0)'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:37:58', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered 'None (0)'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:38:06', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered 'None (0)'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:38:08', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered 'None (0)'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:38:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5'	System	19 Aug 2020 20:38:20
User entered 'No (N)'	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T15:38:16', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a922c77b-0f58-4517-8f79-04acaa2037d5' User entered '19 Aug 2020 15:38'	System	19 Aug 2020 20:38:20
	System	19 Aug 2020 20:38:20

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 13:22'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 15:52'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:28', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'None (0)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:31', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'None (0)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'None (0)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:39', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'None (0)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'None (0)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'None (0)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:51', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered 'No (N)'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-19T23:52:54', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '82a7bb50-f232-491f-aacf-b8734172a0bd' User entered '19 Aug 2020 23:52'	System	20 Aug 2020 04:52:57
	System	20 Aug 2020 04:52:57

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '19 Aug 2020 16:47'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 2'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:48:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc'	System	21 Aug 2020 02:51:25
User entered 'None (0)'	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:49:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc'	System	21 Aug 2020 02:51:25
User entered 'None (0)'	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:49:39', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc'	System	21 Aug 2020 02:51:25
User entered 'None (0)'	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:49:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc' User entered 'None (0)'	System	21 Aug 2020 02:51:25
	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:51:12', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc' User entered 'None (0)'	System	21 Aug 2020 02:51:25
	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:51:15', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc' User entered 'None (0)'	System	21 Aug 2020 02:51:25
	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:51:20', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc'	System	21 Aug 2020 02:51:25
User entered 'No (N)'	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-20T21:51:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'e000f231-0d25-4ce3-a378-e47ef450a3bc'	System	21 Aug 2020 02:51:25
User entered '20 Aug 2020 21:51'	System	21 Aug 2020 02:51:25

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 3'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b' User entered 'None (0)'	System	22 Aug 2020 03:05:53
	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b' User entered 'None (0)'	System	22 Aug 2020 03:05:53
	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:22', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b'	System	22 Aug 2020 03:05:53
User entered 'No interference with activity (1)'	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:31', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b'	System	22 Aug 2020 03:05:53
User entered 'No interference with activity (1)'	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:36', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b' User entered 'None (0)'	System	22 Aug 2020 03:05:53
	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:38', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b' User entered 'None (0)'	System	22 Aug 2020 03:05:53
	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:42', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b' User entered 'No (N)'	System	22 Aug 2020 03:05:53
	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-21T22:05:51', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b0052c65-55f5-4d0f-84fb-020283d9747b' User entered '21 Aug 2020 22:05'	System	22 Aug 2020 03:05:53
	System	22 Aug 2020 03:05:53

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 4'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'None (0)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:10', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'None (0)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:12', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'None (0)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:24', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'None (0)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:26', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'None (0)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:28', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'None (0)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:31', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered 'No (N)'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-22T23:37:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '502a4494-93e7-4384-83d6-21161c3aa2fe' User entered '22 Aug 2020 23:37'	System	23 Aug 2020 04:37:47
	System	23 Aug 2020 04:37:47

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 5'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'None (0)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'None (0)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:47', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'None (0)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'None (0)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:50', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'None (0)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'None (0)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:57', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered 'No (N)'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-23T23:59:59', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9b809b0f-4593-4325-a17e-e03943ab542a' User entered '23 Aug 2020 23:59'	System	24 Aug 2020 05:00:04
	System	24 Aug 2020 05:00:04

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 6'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:08', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'None (0)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'None (0)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:10', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'None (0)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'None (0)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:13', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'None (0)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'None (0)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:17', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed' User entered 'No (N)'	System	25 Aug 2020 14:36:22
	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T09:36:19', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '0346f225-4d95-4b5a-ad60-2188ffb382ed'	System	25 Aug 2020 14:36:22
User entered '25 Aug 2020 09:36'	System	25 Aug 2020 14:36:22

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 7'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:38', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57' User entered 'None (0)'	System	26 Aug 2020 04:32:55
	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:40', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57' User entered 'None (0)'	System	26 Aug 2020 04:32:55
	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:42', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57' User entered 'None (0)'	System	26 Aug 2020 04:32:55
	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:43', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57' User entered 'None (0)'	System	26 Aug 2020 04:32:55
	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57' User entered 'None (0)'	System	26 Aug 2020 04:32:55
	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:47', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57' User entered 'None (0)'	System	26 Aug 2020 04:32:55
	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

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)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:51', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57'	System	26 Aug 2020 04:32:55
User entered 'No (N)'	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-08-25T23:32:53', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7dc2b4d9-58b1-483b-bdd9-460dfdb39c57'	System	26 Aug 2020 04:32:55
User entered '25 Aug 2020 23:32'	System	26 Aug 2020 04:32:55

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:16:40

US3572027

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	02 Sep 2020 19:39:23

US3572027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '26 Aug 2020'	(b) (4) Jackie Ziegler (b) (4)	02 Sep 2020 19:39:23

US3572027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	02 Sep 2020 19:39:23

US3572027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	02 Sep 2020 19:39:23

US3572027

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	02 Sep 2020 19:39:29

US3572027

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'l'	System	02 Sep 2020 19:39:29

US3572027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	03 Sep 2020 19:28:33

US3572027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '3 Sep 2020'	(b) (4) Jackie Ziegler (b) (4)	03 Sep 2020 19:28:33

US3572027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	03 Sep 2020 19:28:33

US3572027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	03 Sep 2020 19:28:33

US3572027

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	03 Sep 2020 19:28:37

US3572027

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User entered 'l'	System	03 Sep 2020 19:28:37

US3572027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	09 Sep 2020 17:43:49

US3572027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '10 Sep 2020' reason for change: New Information	(b) (4)	
	Jackie Ziegler (b) (4)	10 Sep 2020 13:55:38
User entered '9 Sep 2020'	(b) (4)	
	Jasmine Ali (b) (4)	09 Sep 2020 17:43:49
	(b) (4)	

US3572027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 13:55:38
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Jasmine Ali (b) (4)	09 Sep 2020 17:43:49

US3572027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty; reason for change New Information	(b) (4)	
	Jackie Ziegler (b) (4)	10 Sep 2020 13:55:38
User entered 'VM @ 12:43P 9/9/2020. VM @ 4:06O 9/9/2020' reason for change: New Information	Jasmine Ali (b) (4)	09 Sep 2020 21:07:26
	(b) (4)	
User entered 'vm @ 12:43P 9/9/2020'	Jasmine Ali (b) (4)	09 Sep 2020 17:43:49
	(b) (4)	

US3572027

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 13:55:43

US3572027

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:01
User entered 'I'	System	10 Sep 2020 13:55:43

US3572027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:16:48

US3572027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:16:48

US3572027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:16:48

US3572027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'VISIT2'	System	01 Oct 2020 22:16:48

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '07:45'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '23 Sep 2020 07:45'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '98.1' F	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '76'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'bpm'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '18'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'breaths/min'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '114'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'mmHg'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '75'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'mmHg'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '09:10'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '23 Sep 2020 09:10'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '97.9' F	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '88'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'bpm'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '18'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'breaths/min'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '118'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'mmHg'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '71'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'mmHg'	System	01 Oct 2020 22:19:28

US3572027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:43

US3572027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:19:43

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Urine (URINE)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Negative (NEGATIVE)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date has been recorded. Kindly update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 05:54:40
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date has been recorded. Kindly update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:50:06
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date has been recorded. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:53:58
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 07:49:55
User entered '23 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 07:49:55
User entered '08:30'	(b) (4), (b) (6)	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered empty.	System	30 Dec 2020 07:49:55
User entered '23 Sep 2020 08:30'	System	01 Oct 2020 22:21:12

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '8:40'	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '23 Sep 2020 8:40'	System	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'ONCE'	System	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 13:42:17

US3572027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:34

US3572027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:34

US3572027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '07:53'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:34

US3572027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '23 Sep 2020 07:53'	System	01 Oct 2020 22:21:34

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '08:20'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '23 Sep 2020 08:20'	System	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered empty.	System	01 Oct 2020 22:21:54

US3572027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:22:04

US3572027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'I'	System	01 Oct 2020 22:22:04

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'eb8ec35a-57ac-466d-8f8a-dc0f6542142f' User entered 'Yes (Y)'	System	23 Sep 2020 14:07:27
	System	23 Sep 2020 14:07:27

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:15', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'eb8ec35a-57ac-466d-8f8a-dc0f6542142f' User entered '97.4'	System	23 Sep 2020 14:07:27
	System	23 Sep 2020 14:07:27

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:18', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'eb8ec35a-57ac-466d-8f8a-dc0f6542142f' User entered 'No (N)'	System	23 Sep 2020 14:07:27
	System	23 Sep 2020 14:07:27

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'eb8ec35a-57ac-466d-8f8a-dc0f6542142f' User entered '23 Sep 2020 09:07'	System	23 Sep 2020 14:07:27
	System	23 Sep 2020 14:07:27

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 09:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 11:30'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:41:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd6134aa2-126e-4278-a1a3-29c9132a1df5'	System	24 Sep 2020 03:41:55
User entered 'Yes (Y)'	System	24 Sep 2020 03:41:55

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:41:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd6134aa2-126e-4278-a1a3-29c9132a1df5' User entered '98.0'	System	24 Sep 2020 03:41:55
	System	24 Sep 2020 03:41:55

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:41:51', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd6134aa2-126e-4278-a1a3-29c9132a1df5'	System	24 Sep 2020 03:41:55
User entered 'No (N)'	System	24 Sep 2020 03:41:55

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:41:54', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd6134aa2-126e-4278-a1a3-29c9132a1df5' User entered '23 Sep 2020 22:41'	System	24 Sep 2020 03:41:55
	System	24 Sep 2020 03:41:55

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 12:25'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 2'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:33:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c02785dc-6763-45ce-8472-0f6ffa27b1f9' User entered 'Yes (Y)'	System	25 Sep 2020 02:34:10
	System	25 Sep 2020 02:34:10

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:33:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c02785dc-6763-45ce-8472-0f6ffa27b1f9' User entered '98.8'	System	25 Sep 2020 02:34:10
	System	25 Sep 2020 02:34:10

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:33:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c02785dc-6763-45ce-8472-0f6ffa27b1f9'	System	25 Sep 2020 02:34:10
User entered 'Yes (Y)'	System	25 Sep 2020 02:34:10

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User closed query 'Per CDM; Kindly, update the conmed page accordingly with Motrin and specify the log line number.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:06:13
Query 'Per CDM; Kindly, update the conmed page accordingly with Motrin and specify the log line number.' answered with 'Source reviewed; no documentation of pt taking Motrin. Please confirm.' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	10 Oct 2020 21:34:57
User opened query 'Per CDM; Kindly, update the conmed page accordingly with Motrin and specify the log line number.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:41:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 12:37:21
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'motrin 600 mg' (Site from System).	Jessica McDowell (b) (4) (b) (4)	02 Oct 2020 21:22:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 02:34:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:33:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c02785dc-6763-45ce-8472-0f6ffa27b1f9'	System	25 Sep 2020 02:34:10
User entered '1'	System	25 Sep 2020 02:34:10

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:33:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c02785dc-6763-45ce-8472-0f6ffa27b1f9' User entered '0'	System	25 Sep 2020 02:34:10
	System	25 Sep 2020 02:34:10

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:34:07', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c02785dc-6763-45ce-8472-0f6ffa27b1f9' User entered '24 Sep 2020 21:34'	System	25 Sep 2020 02:34:10
	System	25 Sep 2020 02:34:10

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 3'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:43:32', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '026aa246-cff1-4899-bebf-5614e9a7f0f5'	System	26 Sep 2020 14:43:45
User entered 'Yes (Y)'	System	26 Sep 2020 14:43:45

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:43:37', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '026aa246-cff1-4899-bebf-5614e9a7f0f5' User entered '97.9'	System	26 Sep 2020 14:43:45
	System	26 Sep 2020 14:43:45

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:43:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '026aa246-cff1-4899-bebf-5614e9a7f0f5'	System	26 Sep 2020 14:43:45
User entered 'No (N)'	System	26 Sep 2020 14:43:45

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:43:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '026aa246-cff1-4899-bebf-5614e9a7f0f5'	System	26 Sep 2020 14:43:45
User entered '26 Sep 2020 09:43'	System	26 Sep 2020 14:43:45

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 4'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:18', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '435540e8-54e5-4b72-901a-365f82ab7f3e' User entered 'Yes (Y)'	System	27 Sep 2020 14:20:29
	System	27 Sep 2020 14:20:29

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:21', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '435540e8-54e5-4b72-901a-365f82ab7f3e' User entered '97.8'	System	27 Sep 2020 14:20:29
	System	27 Sep 2020 14:20:29

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:24', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '435540e8-54e5-4b72-901a-365f82ab7f3e'	System	27 Sep 2020 14:20:29
User entered 'No (N)'	System	27 Sep 2020 14:20:29

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:26', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '435540e8-54e5-4b72-901a-365f82ab7f3e' User entered '27 Sep 2020 09:20'	System	27 Sep 2020 14:20:29
	System	27 Sep 2020 14:20:29

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 5'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:07', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3924b91-d3e2-4b5c-b966-16e2b8546f48' User entered 'Yes (Y)'	System	28 Sep 2020 03:00:19
	System	28 Sep 2020 03:00:19

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3924b91-d3e2-4b5c-b966-16e2b8546f48' User entered '97.4'	System	28 Sep 2020 03:00:19
	System	28 Sep 2020 03:00:19

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:13', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3924b91-d3e2-4b5c-b966-16e2b8546f48' User entered 'No (N)'	System	28 Sep 2020 03:00:19
	System	28 Sep 2020 03:00:19

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:15', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3924b91-d3e2-4b5c-b966-16e2b8546f48' User entered '27 Sep 2020 22:00'	System	28 Sep 2020 03:00:19
	System	28 Sep 2020 03:00:19

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 6'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:13:59', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a90849f-c0b0-4743-b1b0-b4d61004c2bd' User entered 'Yes (Y)'	System	29 Sep 2020 03:14:12
	System	29 Sep 2020 03:14:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a90849f-c0b0-4743-b1b0-b4d61004c2bd' User entered '96.6'	System	29 Sep 2020 03:14:12
	System	29 Sep 2020 03:14:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a90849f-c0b0-4743-b1b0-b4d61004c2bd' User entered 'No (N)'	System	29 Sep 2020 03:14:12
	System	29 Sep 2020 03:14:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a90849f-c0b0-4743-b1b0-b4d61004c2bd' User entered '28 Sep 2020 22:14'	System	29 Sep 2020 03:14:12
	System	29 Sep 2020 03:14:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 7'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:01:43', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3e52211-c571-4c0b-a527-eadf2794548d' User entered 'Yes (Y)'	System	30 Sep 2020 14:03:12
	System	30 Sep 2020 14:03:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:06', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3e52211-c571-4c0b-a527-eadf2794548d' User entered '97.2'	System	30 Sep 2020 14:03:12
	System	30 Sep 2020 14:03:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:08', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3e52211-c571-4c0b-a527-eadf2794548d' User entered 'No (N)'	System	30 Sep 2020 14:03:12
	System	30 Sep 2020 14:03:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:10', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'b3e52211-c571-4c0b-a527-eadf2794548d' User entered '30 Sep 2020 09:03'	System	30 Sep 2020 14:03:12
	System	30 Sep 2020 14:03:12

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:30', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'debcfdf6-b2ce-4aa1-a078-4ba436a6977a'	System	23 Sep 2020 14:07:44
User entered 'None (1)'	System	23 Sep 2020 14:07:44

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:32', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'debcfdf6-b2ce-4aa1-a078-4ba436a6977a' User entered 'No (N)'	System	23 Sep 2020 14:07:44
	System	23 Sep 2020 14:07:44

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:35', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'debcfdf6-b2ce-4aa1-a078-4ba436a6977a'	System	23 Sep 2020 14:07:44
User entered 'No (N)'	System	23 Sep 2020 14:07:44

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:38', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'debcfdf6-b2ce-4aa1-a078-4ba436a6977a'	System	23 Sep 2020 14:07:44
User entered 'None (1)'	System	23 Sep 2020 14:07:44

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:40', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'debcbdf6-b2ce-4aa1-a078-4ba436a6977a' User entered '23 Sep 2020 09:07'	System	23 Sep 2020 14:07:44
	System	23 Sep 2020 14:07:44

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 09:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 11:30'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:33:49', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '436f12f2-73f3-4bf4-8688-bfd740817d0e'	System	24 Sep 2020 03:34:13
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 03:34:13

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:33:53', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '436f12f2-73f3-4bf4-8688-bfd740817d0e' User entered 'No (N)'	System	24 Sep 2020 03:34:13
	System	24 Sep 2020 03:34:13

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:33:57', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '436f12f2-73f3-4bf4-8688-bfd740817d0e' User entered 'No (N)'	System	24 Sep 2020 03:34:13
	System	24 Sep 2020 03:34:13

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:05', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '436f12f2-73f3-4bf4-8688-bfd740817d0e'	System	24 Sep 2020 03:34:13
User entered 'None (1)'	System	24 Sep 2020 03:34:13

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:08', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '436f12f2-73f3-4bf4-8688-bfd740817d0e'	System	24 Sep 2020 03:34:13
User entered '23 Sep 2020 22:34'	System	24 Sep 2020 03:34:13

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 12:25'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 2'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:34:20', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '05038f6c-cbaa-409e-b2d4-f09a11c66773'	System	25 Sep 2020 03:38:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	25 Sep 2020 03:38:40

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:34:54', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '05038f6c-cbaa-409e-b2d4-f09a11c66773' User entered 'No (N)'	System	25 Sep 2020 03:38:40
	System	25 Sep 2020 03:38:40

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T21:34:58', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '05038f6c-cbaa-409e-b2d4-f09a11c66773'	System	25 Sep 2020 03:38:40
User entered 'Yes (Y)'	System	25 Sep 2020 03:38:40

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:38:02', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '05038f6c-cbaa-409e-b2d4-f09a11c66773' User entered '3'	System	25 Sep 2020 03:38:40
	System	25 Sep 2020 03:38:40

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:38:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '05038f6c-cbaa-409e-b2d4-f09a11c66773'	System	25 Sep 2020 03:38:40
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 03:38:40

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:38:37', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '05038f6c-cbaa-409e-b2d4-f09a11c66773' User entered '24 Sep 2020 22:38'	System	25 Sep 2020 03:38:40
	System	25 Sep 2020 03:38:40

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 3'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:43:56', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3'	System	26 Sep 2020 14:47:49
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:44:07', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3' User entered 'Yes (Y)'	System	26 Sep 2020 14:47:49
	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:01', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3' User entered '3'	System	26 Sep 2020 14:47:49
	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:20', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3' User entered 'Yes (Y)'	System	26 Sep 2020 14:47:49
	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3' User entered '3'	System	26 Sep 2020 14:47:49
	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3' User entered 'None (1)'	System	26 Sep 2020 14:47:49
	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9ff45bc1-ce27-41da-b8af-f8bb061048a3' User entered '26 Sep 2020 09:47'	System	26 Sep 2020 14:47:49
	System	26 Sep 2020 14:47:49

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 4'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '22280c49-92dd-4f6d-9db0-5c2e2811c7eb' User entered 'None (1)'	System	27 Sep 2020 14:20:55
	System	27 Sep 2020 14:20:55

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '22280c49-92dd-4f6d-9db0-5c2e2811c7eb' User entered 'No (N)'	System	27 Sep 2020 14:20:55
	System	27 Sep 2020 14:20:55

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:50', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '22280c49-92dd-4f6d-9db0-5c2e2811c7eb' User entered 'No (N)'	System	27 Sep 2020 14:20:55
	System	27 Sep 2020 14:20:55

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '22280c49-92dd-4f6d-9db0-5c2e2811c7eb' User entered 'None (1)'	System	27 Sep 2020 14:20:55
	System	27 Sep 2020 14:20:55

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:54', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '22280c49-92dd-4f6d-9db0-5c2e2811c7eb' User entered '27 Sep 2020 09:20'	System	27 Sep 2020 14:20:55
	System	27 Sep 2020 14:20:55

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 5'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:19', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bb6aa460-8f6e-45d6-b500-6a4658782407'	System	28 Sep 2020 03:00:30
User entered 'None (1)'	System	28 Sep 2020 03:00:30

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:21', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bb6aa460-8f6e-45d6-b500-6a4658782407' User entered 'No (N)'	System	28 Sep 2020 03:00:30
	System	28 Sep 2020 03:00:30

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:25', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bb6aa460-8f6e-45d6-b500-6a4658782407' User entered 'No (N)'	System	28 Sep 2020 03:00:30
	System	28 Sep 2020 03:00:30

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bb6aa460-8f6e-45d6-b500-6a4658782407'	System	28 Sep 2020 03:00:30
User entered 'None (1)'	System	28 Sep 2020 03:00:30

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:29', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bb6aa460-8f6e-45d6-b500-6a4658782407'	System	28 Sep 2020 03:00:30
User entered '27 Sep 2020 22:00'	System	28 Sep 2020 03:00:30

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 6'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8fc3db88-bf2c-4aac-849e-02dad1850bdd'	System	29 Sep 2020 03:14:26
User entered 'None (1)'	System	29 Sep 2020 03:14:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:16', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8fc3db88-bf2c-4aac-849e-02dad1850bdd' User entered 'No (N)'	System	29 Sep 2020 03:14:26
	System	29 Sep 2020 03:14:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:19', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8fc3db88-bf2c-4aac-849e-02dad1850bdd' User entered 'No (N)'	System	29 Sep 2020 03:14:26
	System	29 Sep 2020 03:14:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:21', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8fc3db88-bf2c-4aac-849e-02dad1850bdd'	System	29 Sep 2020 03:14:26
User entered 'None (1)'	System	29 Sep 2020 03:14:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '8fc3db88-bf2c-4aac-849e-02dad1850bdd' User entered '28 Sep 2020 22:14'	System	29 Sep 2020 03:14:26
	System	29 Sep 2020 03:14:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 7'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:13', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '700f2f2e-f0d6-4730-a14d-330c14152b82'	System	30 Sep 2020 14:03:26
User entered 'None (1)'	System	30 Sep 2020 14:03:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:15', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '700f2f2e-f0d6-4730-a14d-330c14152b82'	System	30 Sep 2020 14:03:26
User entered 'No (N)'	System	30 Sep 2020 14:03:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:18', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '700f2f2e-f0d6-4730-a14d-330c14152b82'	System	30 Sep 2020 14:03:26
User entered 'No (N)'	System	30 Sep 2020 14:03:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:20', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '700f2f2e-f0d6-4730-a14d-330c14152b82'	System	30 Sep 2020 14:03:26
User entered 'None (1)'	System	30 Sep 2020 14:03:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:22', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '700f2f2e-f0d6-4730-a14d-330c14152b82'	System	30 Sep 2020 14:03:26
User entered '30 Sep 2020 09:03'	System	30 Sep 2020 14:03:26

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'None (0)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'None (0)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'None (0)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:50', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'None (0)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'None (0)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:07:53', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'None (0)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:08:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8' User entered 'No (N)'	System	23 Sep 2020 14:08:07
	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T09:08:01', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'bed2e3de-21e9-49f9-85c3-45a5451029a8'	System	23 Sep 2020 14:08:07
User entered '23 Sep 2020 09:08'	System	23 Sep 2020 14:08:07

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 09:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 11:30'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:15', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b' User entered 'None (0)'	System	24 Sep 2020 03:34:58
	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:22', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b'	System	24 Sep 2020 03:34:58
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:39', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b'	System	24 Sep 2020 03:34:58
User entered 'No interference with activity (1)'	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:43', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b'	System	24 Sep 2020 03:34:58
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b' User entered 'None (0)'	System	24 Sep 2020 03:34:58
	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b' User entered 'None (0)'	System	24 Sep 2020 03:34:58
	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b' User entered 'No (N)'	System	24 Sep 2020 03:34:58
	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-23T22:34:55', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '14e807db-43c3-4593-9506-e3f3d7bdc59b' User entered '23 Sep 2020 22:34'	System	24 Sep 2020 03:34:58
	System	24 Sep 2020 03:34:58

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '23 Sep 2020 12:25'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 2'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:39:04', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829'	System	25 Sep 2020 03:40:39
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:39:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829'	System	25 Sep 2020 03:40:39
User entered 'Some interference with activity (2)'	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:39:29', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829'	System	25 Sep 2020 03:40:39
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:39:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829'	System	25 Sep 2020 03:40:39
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:39:36', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829' User entered 'None (0)'	System	25 Sep 2020 03:40:39
	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:40:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829'	System	25 Sep 2020 03:40:39
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:40:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829'	System	25 Sep 2020 03:40:39
User entered 'No (N)'	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-24T22:40:37', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'ba0b3a76-62c9-439e-bc5e-0cc9241a9829' User entered '24 Sep 2020 22:40'	System	25 Sep 2020 03:40:39
	System	25 Sep 2020 03:40:39

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 3'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:54', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'None (0)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:56', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'None (0)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:47:58', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'None (0)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:48:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'None (0)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:48:02', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'None (0)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:48:04', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'None (0)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:48:07', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered 'No (N)'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-26T09:48:09', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3eaa4101-283f-459a-9fd5-f6e384680fcd' User entered '26 Sep 2020 09:48'	System	26 Sep 2020 14:48:12
	System	26 Sep 2020 14:48:12

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 4'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:57', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'None (0)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:20:59', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'None (0)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:21:01', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'None (0)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:21:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'None (0)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:21:05', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'None (0)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:21:17', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'None (0)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:21:22', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered 'No (N)'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T09:21:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '7d666c92-326b-462b-b93c-a10035b1afac' User entered '27 Sep 2020 09:21'	System	27 Sep 2020 14:21:28
	System	27 Sep 2020 14:21:28

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 5'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:31', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'None (0)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:33', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'None (0)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'None (0)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:36', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'None (0)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:37', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'None (0)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'None (0)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:45', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered 'No (N)'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-27T22:00:47', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '04903da5-a97a-4f6c-bf34-8f34efa63574' User entered '27 Sep 2020 22:00'	System	28 Sep 2020 03:00:49
	System	28 Sep 2020 03:00:49

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 6'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:26', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'None (0)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:28', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'None (0)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:29', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'None (0)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:31', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'None (0)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:32', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'None (0)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'None (0)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:41', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered 'No (N)'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-28T22:14:43', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f105c055-2b80-4554-8fbb-9c4bc7d27aee' User entered '28 Sep 2020 22:14'	System	29 Sep 2020 03:14:48
	System	29 Sep 2020 03:14:48

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	23 Sep 2020 13:42:17
User entered 'Day 7'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:24', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered 'None (0)'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:26', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered 'None (0)'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered 'None (0)'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:29', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered 'None (0)'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:30', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered 'None (0)'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:31', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered 'None (0)'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98'	System	30 Sep 2020 14:03:40
User entered 'No (N)'	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-09-30T09:03:37', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'cbce0577-9ba2-4609-b646-15c8e9987d98' User entered '30 Sep 2020 09:03'	System	30 Sep 2020 14:03:40
	System	30 Sep 2020 14:03:40

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 13:42:17

US3572027

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 13:42:17

US3572027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 21:22:00

US3572027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '2 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 21:22:00

US3572027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	02 Oct 2020 21:22:00

US3572027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered empty.	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 21:22:00

US3572027

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 21:22:05

US3572027

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'l'	System	02 Oct 2020 21:22:05

US3572027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	14 Oct 2020 13:38:50

US3572027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:30:10
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Jessica McDowell (b) (4)	14 Oct 2020 13:39:05
answered with '4 day oow ' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Oct 2020 13:38:50
User entered '14 Oct 2020'	Jessica McDowell (b) (4)	14 Oct 2020 13:38:50
	(b) (4)	

US3572027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	14 Oct 2020 13:38:50

US3572027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered empty.	Jessica McDowell (b) (4) (b) (4)	14 Oct 2020 13:38:50

US3572027

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Maria Candelario (b) (4)	28 Oct 2020 01:23:49
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	14 Oct 2020 13:39:20
	(b) (4)	

US3572027

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'l'	System	28 Oct 2020 01:23:49
User entered empty.	System	14 Oct 2020 13:39:20

US3572027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	14 Dec 2020 16:55:54

US3572027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	14 Dec 2020 16:56:20
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	14 Dec 2020 16:56:20
User entered '16 Oct 2020' reason for change: Data Entry Error	Jessica McDowell (b) (4) (b) (4)	14 Dec 2020 16:56:20
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Dec 2020 16:55:54
User entered '21 Oct 2020'	Jessica McDowell (b) (4) (b) (4)	14 Dec 2020 16:55:54

US3572027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	24 Feb 2021 04:08:49
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessica McDowell (b) (4) (b) (4)	14 Dec 2020 16:55:54

US3572027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'unable to reach'	(b) (4) Jessica McDowell (b) (4) (b) (4)	14 Dec 2020 16:55:54

US3572027

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:24:04

US3572027

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'l'	System	28 Oct 2020 01:24:04

US3572027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:24:17

US3572027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '26 Oct 2020'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:24:17

US3572027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Clinic (Clinic)'	(b) (4) Maria Candelario (b) (4) (b) (4)	28 Oct 2020 01:24:17

US3572027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'VISIT3'	System	28 Oct 2020 01:24:17

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '26 Oct 2020'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '09:00'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '26 Oct 2020 09:00'	System	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '97.5' F	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Other (Other)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'temporal'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '73'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'bpm'	System	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '20'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'breaths/min'	System	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '115'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'mmHg'	System	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '76'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'mmHg'	System	28 Oct 2020 01:25:03

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11

US3572027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11

US3572027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:18

US3572027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '26 Oct 2020'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:18

US3572027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:47

US3572027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '26 Oct 2020'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:47

US3572027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered '09:57'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:47

US3572027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered '26 Oct 2020 09:57'	System	28 Oct 2020 01:25:47

US3572027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:08:49
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	28 Oct 2020 01:25:53

US3572027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:11
User entered 'I'	System	28 Oct 2020 01:25:53

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 64'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-19T00:01:35', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '52636246-4b94-454a-b8e3-0e2d57ba55d0'	System	19 Oct 2020 05:02:32
User entered 'Yes (Y)'	System	19 Oct 2020 05:02:32

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-19T00:01:49', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '52636246-4b94-454a-b8e3-0e2d57ba55d0'	System	19 Oct 2020 05:02:32
User entered 'No (N)'	System	19 Oct 2020 05:02:32

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-19T00:02:01', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '52636246-4b94-454a-b8e3-0e2d57ba55d0'	System	19 Oct 2020 05:02:32
User entered 'No (N)'	System	19 Oct 2020 05:02:32

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-19T00:02:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '52636246-4b94-454a-b8e3-0e2d57ba55d0'	System	19 Oct 2020 05:02:32
User entered 'No (N)'	System	19 Oct 2020 05:02:32

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-19T00:02:28', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '52636246-4b94-454a-b8e3-0e2d57ba55d0' User entered '19 Oct 2020 00:02:28'	System	19 Oct 2020 05:02:32
	System	19 Oct 2020 05:02:32

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 71'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-29T18:23:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df2c7692-96d4-4ab8-bf5d-86d8dc08edf4'	System	29 Oct 2020 23:24:00
User entered 'No (N)'	System	29 Oct 2020 23:24:00

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-29T18:23:42', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df2c7692-96d4-4ab8-bf5d-86d8dc08edf4'	System	29 Oct 2020 23:24:00
User entered 'Yes (Y)'	System	29 Oct 2020 23:24:00

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-29T18:23:48', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df2c7692-96d4-4ab8-bf5d-86d8dc08edf4'	System	29 Oct 2020 23:24:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Oct 2020 23:24:00

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-10-29T18:23:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df2c7692-96d4-4ab8-bf5d-86d8dc08edf4' User entered '29 Oct 2020 18:23:52'	System	29 Oct 2020 23:24:00
	System	29 Oct 2020 23:24:00

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 78'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-02T11:06:49', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '21e22855-2a35-47f2-bd0b-2c5ba912b4e7'	System	02 Nov 2020 17:06:58
User entered 'No (N)'	System	02 Nov 2020 17:06:58

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-02T11:06:53', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '21e22855-2a35-47f2-bd0b-2c5ba912b4e7'	System	02 Nov 2020 17:06:58
User entered 'No (N)'	System	02 Nov 2020 17:06:58

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-02T11:06:55', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '21e22855-2a35-47f2-bd0b-2c5ba912b4e7' User entered '02 Nov 2020 11:06:55'	System	02 Nov 2020 17:06:58
	System	02 Nov 2020 17:06:58

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 18:16:40

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered 'Day 92'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-16T09:01:52', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f8c53c04-bc02-40c8-a5a3-d77d789acb3d' User entered 'Yes (Y)'	System	16 Nov 2020 15:02:19
	System	16 Nov 2020 15:02:19

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-16T09:01:59', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f8c53c04-bc02-40c8-a5a3-d77d789acb3d'	System	16 Nov 2020 15:02:19
User entered 'No (N)'	System	16 Nov 2020 15:02:19

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-16T09:02:03', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f8c53c04-bc02-40c8-a5a3-d77d789acb3d'	System	16 Nov 2020 15:02:19
User entered 'No (N)'	System	16 Nov 2020 15:02:19

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-16T09:02:11', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f8c53c04-bc02-40c8-a5a3-d77d789acb3d' User entered 'No (N)'	System	16 Nov 2020 15:02:19
	System	16 Nov 2020 15:02:19

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-16T09:02:14', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'f8c53c04-bc02-40c8-a5a3-d77d789acb3d' User entered '16 Nov 2020 09:02:14'	System	16 Nov 2020 15:02:19
	System	16 Nov 2020 15:02:19

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 18:16:40

US3572027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:27:55
Data entry locked.	System	19 Aug 2020 18:16:40
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 18:16:40

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-23T06:48:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c15542f6-abd8-430b-84d4-cb2362630c86'	System	23 Nov 2020 12:49:04
User entered 'No (N)'	System	23 Nov 2020 12:49:04

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-23T06:48:50', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c15542f6-abd8-430b-84d4-cb2362630c86'	System	23 Nov 2020 12:49:04
User entered 'No (N)'	System	23 Nov 2020 12:49:04

US3572027

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 (D3D16E9F-0375-48F5-AC9A-7DCBA1568E89)', Time: '2020-11-23T06:48:53', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c15542f6-abd8-430b-84d4-cb2362630c86' User entered '23 Nov 2020 06:48:53'	System	23 Nov 2020 12:49:04
	System	23 Nov 2020 12:49:04

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:07:22

US3572027

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 23:07:22
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:07:22

US3572027

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 23:07:22
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

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 23:07:22
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-26T09:55:36', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '2b689745-e815-413b-8d30-c1787015ea2f' User entered 'No (N)'	System	26 Jan 2021 15:56:15
	System	26 Jan 2021 15:56:15

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-26T09:55:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '2b689745-e815-413b-8d30-c1787015ea2f' User entered 'No (N)'	System	26 Jan 2021 15:56:15
	System	26 Jan 2021 15:56:15

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-26T09:55:49', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '2b689745-e815-413b-8d30-c1787015ea2f' User entered '26 Jan 2021 09:55:49'	System	26 Jan 2021 15:56:15

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-29T00:02:39', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '81b972b8-055b-47e7-bdb4-cab4ec2ab85b'	System	29 Jan 2021 06:04:13
User entered 'Yes (Y)'	System	29 Jan 2021 06:04:13

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-29T00:02:47', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '81b972b8-055b-47e7-bdb4-cab4ec2ab85b' User entered 'Yes (Y)'	System	29 Jan 2021 06:04:13
	System	29 Jan 2021 06:04:13

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-29T00:02:57', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '81b972b8-055b-47e7-bdb4-cab4ec2ab85b'	System	29 Jan 2021 06:04:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 06:04:13

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-29T00:03:04', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '81b972b8-055b-47e7-bdb4-cab4ec2ab85b'	System	29 Jan 2021 06:04:13
User entered 'No (N)'	System	29 Jan 2021 06:04:13

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-29T00:03:58', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '81b972b8-055b-47e7-bdb4-cab4ec2ab85b'	System	29 Jan 2021 06:04:13
User entered 'No (N)'	System	29 Jan 2021 06:04:13

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-01-29T00:04:02', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '81b972b8-055b-47e7-bdb4-cab4ec2ab85b' User entered '29 Jan 2021 00:04:02'	System	29 Jan 2021 06:04:13
	System	29 Jan 2021 06:04:13

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:16', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6' User entered 'Yes (Y)'	System	06 Feb 2021 00:49:00
	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6' User entered 'Yes (Y)'	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:27', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6'	System	06 Feb 2021 00:49:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6' User entered 'No (N)'	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:44', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6' User entered 'Yes (Y)'	System	06 Feb 2021 00:49:00
	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:46', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6'	System	06 Feb 2021 00:49:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-05T18:48:49', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c49a8d6b-4056-4904-bacb-5af4d54366f6' User entered '05 Feb 2021 18:48:49'	System	06 Feb 2021 00:49:00
	System	06 Feb 2021 00:49:00

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-12T06:52:16', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a414f84-2284-4f56-b1d6-454c51042762' User entered 'No (N)'	System	12 Feb 2021 12:52:25
	System	12 Feb 2021 12:52:25

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-12T06:52:20', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a414f84-2284-4f56-b1d6-454c51042762' User entered 'No (N)'	System	12 Feb 2021 12:52:25
	System	12 Feb 2021 12:52:25

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-12T06:52:23', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5a414f84-2284-4f56-b1d6-454c51042762' User entered '12 Feb 2021 06:52:23'	System	12 Feb 2021 12:52:25
	System	12 Feb 2021 12:52:25

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-20T08:50:32', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a66f54c8-f198-419c-9fc4-113f0bb4245d' User entered 'No (N)'	System	20 Feb 2021 14:50:41

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-20T08:50:34', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a66f54c8-f198-419c-9fc4-113f0bb4245d' User entered 'No (N)'	System	20 Feb 2021 14:50:41

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-20T08:50:37', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'a66f54c8-f198-419c-9fc4-113f0bb4245d' User entered '20 Feb 2021 08:50:37'	System	20 Feb 2021 14:50:41
	System	20 Feb 2021 14:50:41

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-26T12:03:59-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df986a5e-06a0-4438-93d4-eb3509dfe29e' User entered 'No (N)'	System	26 Feb 2021 18:09:14
	System	26 Feb 2021 18:09:14

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-26T12:04:02-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df986a5e-06a0-4438-93d4-eb3509dfe29e' User entered 'No (N)'	System	26 Feb 2021 18:09:14

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-02-26T12:04:04-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'df986a5e-06a0-4438-93d4-eb3509dfe29e'	System	26 Feb 2021 18:09:14
User entered '26 Feb 2021 18:04:04'	System	26 Feb 2021 18:09:14

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-06T18:50:21-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '17c6c4fc-f483-4831-a5e5-40cd5385837e'	System	07 Mar 2021 00:50:30
User entered 'No (N)'	System	07 Mar 2021 00:50:30

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-06T18:50:24-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '17c6c4fc-f483-4831-a5e5-40cd5385837e'	System	07 Mar 2021 00:50:30
User entered 'No (N)'	System	07 Mar 2021 00:50:30

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-06T18:50:26-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '17c6c4fc-f483-4831-a5e5-40cd5385837e'	System	07 Mar 2021 00:50:30
User entered '06 Mar 2021 18:50:26'	System	07 Mar 2021 00:50:30

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-12T09:08:56-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd8d2a421-223c-4da3-8057-4f9182bb3d15'	System	12 Mar 2021 15:09:11
User entered 'No (N)'	System	12 Mar 2021 15:09:11

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-12T09:09:03-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd8d2a421-223c-4da3-8057-4f9182bb3d15'	System	12 Mar 2021 15:09:11
User entered 'No (N)'	System	12 Mar 2021 15:09:11

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-12T09:09:05-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'd8d2a421-223c-4da3-8057-4f9182bb3d15'	System	12 Mar 2021 15:09:11
User entered '12 Mar 2021 09:09:05'	System	12 Mar 2021 15:09:11

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-19T17:50:52-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c011f25f-2183-4f52-b5aa-ed7c88880ec3'	System	19 Mar 2021 22:52:16
User entered 'Yes (Y)'	System	19 Mar 2021 22:52:16

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-19T17:50:59-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c011f25f-2183-4f52-b5aa-ed7c88880ec3'	System	19 Mar 2021 22:52:16
User entered 'No (N)'	System	19 Mar 2021 22:52:16

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-19T17:51:10-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c011f25f-2183-4f52-b5aa-ed7c88880ec3'	System	19 Mar 2021 22:52:16
User entered 'No (N)'	System	19 Mar 2021 22:52:16

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-19T17:51:27-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c011f25f-2183-4f52-b5aa-ed7c88880ec3'	System	19 Mar 2021 22:52:16
User entered 'Yes (Y)'	System	19 Mar 2021 22:52:16

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-19T17:51:35-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c011f25f-2183-4f52-b5aa-ed7c88880ec3'	System	19 Mar 2021 22:52:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 22:52:16

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-19T17:52:01-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: 'c011f25f-2183-4f52-b5aa-ed7c88880ec3'	System	19 Mar 2021 22:52:16
User entered '19 Mar 2021 17:52:01'	System	19 Mar 2021 22:52:16

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-30T07:46:13-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '98853d66-8b6d-439d-9dd7-9884359a9663'	System	30 Mar 2021 12:46:21
User entered 'No (N)'	System	30 Mar 2021 12:46:21

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-30T07:46:16-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '98853d66-8b6d-439d-9dd7-9884359a9663'	System	30 Mar 2021 12:46:21
User entered 'No (N)'	System	30 Mar 2021 12:46:21

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-30T07:46:19-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '98853d66-8b6d-439d-9dd7-9884359a9663'	System	30 Mar 2021 12:46:21
User entered '30 Mar 2021 07:46:19'	System	30 Mar 2021 12:46:21

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-02T09:16:40-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '6057c29d-a22c-47ea-bd97-f203e1f4e037'	System	02 Apr 2021 14:16:52
User entered 'No (N)'	System	02 Apr 2021 14:16:52

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-02T09:16:44-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '6057c29d-a22c-47ea-bd97-f203e1f4e037'	System	02 Apr 2021 14:16:52
User entered 'No (N)'	System	02 Apr 2021 14:16:52

US3572027

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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-02T09:16:47-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '6057c29d-a22c-47ea-bd97-f203e1f4e037'	System	02 Apr 2021 14:16:52
User entered '02 Apr 2021 09:16:47'	System	02 Apr 2021 14:16:52

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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 23:07:22
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-11T19:16:43-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '27d4ce21-4c1e-4859-a69f-a8b1fdcd9ee6' User entered 'No (N)'	System	12 Apr 2021 00:16:53
	System	12 Apr 2021 00:16:53

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-11T19:16:47-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '27d4ce21-4c1e-4859-a69f-a8b1fdcd9ee6'	System	12 Apr 2021 00:16:53
User entered 'No (N)'	System	12 Apr 2021 00:16:53

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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 (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-11T19:16:50-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '27d4ce21-4c1e-4859-a69f-a8b1fdcd9ee6'	System	12 Apr 2021 00:16:53
User entered '11 Apr 2021 19:16:50'	System	12 Apr 2021 00:16:53

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-17T12:47:30-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9d62331b-4a0c-4b04-b37c-2aa9e5a1251f' User entered 'No (N)'	System	17 Apr 2021 17:47:38
	System	17 Apr 2021 17:47:38

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-17T12:47:32-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9d62331b-4a0c-4b04-b37c-2aa9e5a1251f' User entered 'No (N)'	System	17 Apr 2021 17:47:38

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-17T12:47:34-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '9d62331b-4a0c-4b04-b37c-2aa9e5a1251f' User entered '17 Apr 2021 12:47:34'	System	17 Apr 2021 17:47:38
	System	17 Apr 2021 17:47:38

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-25T13:03:56-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '92cbbc07-a7a9-4155-915a-5d6645e29dff' User entered 'No (N)'	System	25 Apr 2021 18:42:41

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-25T13:03:58-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '92cbbc07-a7a9-4155-915a-5d6645e29dff' User entered 'No (N)'	System	25 Apr 2021 18:42:41

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-04-25T13:04:00-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '92cbbc07-a7a9-4155-915a-5d6645e29dff' User entered '25 Apr 2021 13:04:00'	System	25 Apr 2021 18:42:41
	System	25 Apr 2021 18:42:41

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-05-01T16:44:20-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5f7e7228-e2c3-4882-988b-b66fe641cc33'	System	01 May 2021 21:44:27
User entered 'No (N)'	System	01 May 2021 21:44:27

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-05-01T16:44:23-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5f7e7228-e2c3-4882-988b-b66fe641cc33'	System	01 May 2021 21:44:27
User entered 'No (N)'	System	01 May 2021 21:44:27

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-05-01T16:44:25-05:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '5f7e7228-e2c3-4882-988b-b66fe641cc33'	System	01 May 2021 21:44:27
User entered '01 May 2021 16:44:25'	System	01 May 2021 21:44:27

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

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 23:07:22
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:07:22

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:07:22

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:07:22

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:07:22

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Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:07:22

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:07:22

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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 23:07:22
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:07:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:07:22

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:07:22

US3572027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:07:22
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:07:22

US3572027

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:59:11

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 18:03:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-01T01:08:52-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3757bb9c-f0fd-49ea-8945-87b824b868e7'	System	01 Mar 2021 07:08:58
User entered 'No (N)'	System	01 Mar 2021 07:08:58

US3572027

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:59:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:03:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7421A63-8F4E-49A7-9D53-135057075C0A)', Time: '2021-03-01T01:08:55-06:00', User OID: 'PatientReportedOutcome (US3572027)', ODM File OID: '3757bb9c-f0fd-49ea-8945-87b824b868e7' User entered '01 Mar 2021 07:08:55'	System	01 Mar 2021 07:08:58
	System	01 Mar 2021 07:08:58

US3572027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	08 Mar 2021 05:14:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:35:39

US3572027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	08 Mar 2021 05:14:23
User entered '16 Nov 2020'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:35:39

US3572027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	08 Mar 2021 05:14:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:35:39

US3572027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	08 Mar 2021 05:14:23
User entered empty.	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:35:39

US3572027

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User signature succeeded.	Milton Haber (b) (4)	08 Mar 2021 05:14:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:35:43

US3572027

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:39
User entered 'l'	System	16 Nov 2020 19:35:43

US3572027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	19 Jan 2021 21:24:52

US3572027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) System	19 Jan 2021 21:30:21
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	19 Jan 2021 21:30:21
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:30:21
User entered '16 Dec 2020' reason for change: Data Entry Error	Jessica McDowell (b) (4) (b) (4)	19 Jan 2021 21:30:21
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:30:09
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:30:09
User entered '10 Dec 2021' reason for change: Data Entry Error	Jessica McDowell (b) (4) (b) (4)	19 Jan 2021 21:30:09
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:28:16
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:28:16
User entered '16 Dec 2021' reason for change: Data Entry Error	Jessica McDowell (b) (4) (b) (4)	19 Jan 2021 21:28:16
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:28:07
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:28:07
User entered '28 Dec 2021' reason for change: Data Entry Error	Jessica McDowell (b) (4) (b) (4)	19 Jan 2021 21:28:07
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:56
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:56
User entered '30 Dec 2021' reason for change: Data Entry Error	Jessica McDowell (b) (4) (b) (4)	19 Jan 2021 21:27:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

1512 of 1742

US3572027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:48
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:48
User entered '23 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:27:48
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:21
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:21
User entered '16 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:27:21
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:00
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:27:00
User entered '12 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:27:00
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:53
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:53
User entered '10 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:26:53
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:28
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:28
User entered '18 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:26:28
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:20
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:20
User entered '19 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:26:20
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:06
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:26:06
User entered '15 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:26:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3572027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:25:55
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:25:55
User entered '16 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:25:55
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Jan 2021 21:25:35
User entered '19 Dec 2021' reason for change: Data Entry Error	Jessica Mcdowell (b) (4)	19 Jan 2021 21:25:35
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	19 Jan 2021 21:24:52
User entered '19 Jan 2021'	Jessica Mcdowell (b) (4)	19 Jan 2021 21:24:52

US3572027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	Jessica McDowell (b) (4)	19 Jan 2021 21:25:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Jessica McDowell (b) (4)	19 Jan 2021 21:24:52
	(b) (4)	

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Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4) System	19 Jan 2021 21:27:21
Please review and reconcile.' (Site from System).		
User entered 'unable to reach' reason for change:	Jessica McDowell (b) (4)	19 Jan 2021 21:27:21
Data Entry Error	(b) (4)	
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	19 Jan 2021 21:25:35
Please review and reconcile.' (Site from System).		
User entered empty.	Jessica McDowell (b) (4)	19 Jan 2021 21:24:52
	(b) (4)	

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Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	19 Jan 2021 21:30:26

US3572027

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User entered 'l'	System	19 Jan 2021 21:30:26

US3572027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 06:35:25
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 02:03:06
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:15:27
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	19 Jan 2021 21:30:35

US3572027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '19 Jan 2021'	(b) (4) Jessica McDowell (b) (4)	19 Jan 2021 21:30:35

US3572027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	19 Jan 2021 21:30:35

US3572027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Jessica McDowell (b) (4)	19 Jan 2021 21:30:35

US3572027

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	19 Jan 2021 21:30:42

US3572027

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User entered 'l'	System	19 Jan 2021 21:30:42

US3572027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	19 Feb 2021 20:38:59

US3572027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Jessica McDowell (b) (4)	28 Feb 2021 19:56:25
User entered '19 Feb 2021'	(b) (4)	
	Martha Bunnell-Pollak	19 Feb 2021 20:38:59
	(b) (4)	

US3572027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	19 Feb 2021 20:38:59

US3572027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	19 Feb 2021 20:38:59

US3572027

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	19 Feb 2021 20:39:03

US3572027

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:47:40
User entered 'l'	System	19 Feb 2021 20:39:03

US3572027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:03:46
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	21 Apr 2021 01:28:37
	(b) (4)	

US3572027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Apr 2021 01:28:37

US3572027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:03:46
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	21 Apr 2021 01:28:46
	(b) (4)	

US3572027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:03:46
	(b) (4)	
User entered '20 Apr 2021'	Jessica McDowell (b) (4)	21 Apr 2021 01:28:46
	(b) (4)	

US3572027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:03:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	21 Apr 2021 01:28:46

US3572027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:03:46
User entered empty.	(b) (4) Jessica McDowell (b) (4)	21 Apr 2021 01:28:46

US3572027

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:03:46
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	21 Apr 2021 01:30:31
	(b) (4)	

US3572027

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Apr 2021 01:30:31

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '3 Sep 2020'	(b) (4) Jackie Ziegler (b) (4)	03 Sep 2020 19:28:58

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '14:20'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	03 Sep 2020 19:28:58

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User entered '3 Sep 2020 14:20'	System	03 Sep 2020 19:28:58

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Safety Call (Safety Call)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	03 Sep 2020 19:28:58

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	03 Sep 2020 19:28:58
	(b) (4)	

US3572027

Folder: Covid-19 Assessment 03 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:59:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	03 Sep 2020 19:29:04

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '10 Sep 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 13:56:00

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '08:55'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 13:56:00

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User entered '10 Sep 2020 08:55'	System	10 Sep 2020 13:56:00

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Safety Call (Safety Call)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 13:56:00

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 13:56:00

US3572027

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:59:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 13:56:05

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '26 Aug 2020'	(b) (4) Jackie Ziegler (b) (4)	29 Aug 2020 22:18:58

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '15:45'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Aug 2020 22:18:58

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User entered '26 Aug 2020 15:45'	System	29 Aug 2020 22:18:58

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Safety Call (Safety Call)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Aug 2020 22:18:58

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Aug 2020 22:18:58

US3572027

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:59:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:33:53
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Aug 2020 22:19:03

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:00:38

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:00:38

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:00:38

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 02:00:38

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:07:52

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:07:52

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered empty.	System	11 Feb 2021 02:01:43

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:02:15

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:02:15

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '09:15'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:02:15

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '26 Jan 2021 09:15'	System	11 Feb 2021 02:02:15

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:02:37

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:02:37

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '09:11'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:02:37

US3572027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:41:21
User entered '26 Jan 2021 09:11'	System	11 Feb 2021 02:02:37

US3572027

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:59:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:37
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	02 Feb 2021 04:12:48
Query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:30:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 06:30:46
User opened query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).		28 Jan 2021 09:45:31
User entered 'No (N)' reason for change: Data Entry Error	Brett Potthoff (b) (4) (b) (4)	07 Oct 2020 23:58:38
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	29 Aug 2020 22:19:35

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
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)	21 Jan 2021 17:45:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 17:45:05
Data point term sent to Coder	System	21 Jan 2021 17:43:51
User entered 'Anxiety'	Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
	(b) (4)	
User entered '09 Nov 2020'	Alisha Lutat (b) (4)	21 Jan 2021 17:43:48
	(b) (4)	

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	21 Jan 2021 17:44:14
User entered empty; reason for change Data Entry Error	Alisha Lutat (b) (4)	21 Jan 2021 17:44:14
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Jan 2021 17:43:48
User entered '00:00'	Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 17:44:14
User entered '09 Nov 2020 00:00'	System	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User closed query 'Per sponsor review, AE start date is after second dose of IP and Action Taken with IP = None. Please review and update.' (Site from DM).	(b) (4) (u) (4), (b) (6)	08 Feb 2021 09:15:31
Query 'Per sponsor review, AE start date is after second dose of IP and Action Taken with IP = None. Please review and update.' answered with 'data updated' (Site from DM).	Maria Candelario (b) (4) (b) (4)	05 Feb 2021 19:38:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	05 Feb 2021 19:38:11
User opened query 'Per sponsor review, AE start date is after second dose of IP and Action Taken with IP = None. Please review and update.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 17:51:58
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 17:44:14
User entered 'None (NONE)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:43:48
User entered empty.	Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'l'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

US3572027

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:28:33
User entered empty.	(b) (4) Alisha Lutat (b) (4)	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 17:43:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 17:43:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:59:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:54:37
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) and Pain at Injection Site = 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) (u) (4), (b) (6)	23 Feb 2021 11:33:59
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) and Pain at Injection Site = 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. ' answered with 'no medications were reported for dose 2 day 2' (Site from DM).	Caitlin roll (b) (4)	16 Feb 2021 16:41:39
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) and Pain at Injection Site = 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)	09 Feb 2021 06:38:14
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:39:22

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
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)	27 Aug 2020 19:37:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:37:20
Data point term sent to Coder	System	27 Aug 2020 16:41:04
User entered 'Ibuprofen'	Jackie Ziegler (b) (4)	27 Aug 2020 16:40:10

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	02 Apr 2021 04:45:25
User entered 'pain at injection site'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	02 Apr 2021 04:45:25
User entered '400'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	02 Apr 2021 04:45:25
User entered 'mg (mg)'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Aug 2020 16:40:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	02 Apr 2021 04:45:25
User entered 'as needed (PRN)'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Aug 2020 16:40:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	02 Apr 2021 04:45:25
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Aug 2020 16:40:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4) (u) (4), (b) (6)	13 Oct 2020 14:54:00
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' answered with 'data updated ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	10 Oct 2020 21:27:50
User entered '19 Aug 2020' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	10 Oct 2020 21:26:43
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:54:17
User entered '18 Aug 2020'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (u) (4), (b) (6)	13 Oct 2020 14:54:03
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data updated ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	10 Oct 2020 21:28:16
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	10 Oct 2020 21:27:40
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:54:39
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	10 Oct 2020 21:27:40
User entered empty.	Alisha Lutat (b) (4)	10 Oct 2020 21:27:40
	Jackie Ziegler (b) (4)	27 Aug 2020 16:40:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User entered empty.	System	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User entered empty.	System	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:07
User entered empty.	System	27 Aug 2020 16:40:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 09:12:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 09:12:31
Data point term sent to Coder	System	02 Sep 2020 19:34:50
User entered 'Ethinyl Estradiol and Norgestimate'	Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Oral Contraception'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'I'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'tablet (TABLET)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'once daily (QD)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Oral (ORAL)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'UN Jan 2019'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 19:34:29

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:36:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:36:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:25:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:25:56
Data point term sent to Coder User entered 'Protonix'	System (b) (4), (b) (6)	01 Oct 2020 22:25:03 01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'GERD'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '40'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'once daily (QD)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '01 Sep 2019'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 22:24:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:26:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:26:57
Data point term sent to Coder	System	01 Oct 2020 22:26:03
User entered 'Vyvans'	(b) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'ADHD'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '50'	(b) (4) (v) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'once daily (QD)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the MH-ADHD-01 JUN 2019. Please review and reconcile the Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	25 Jan 2021 05:48:45
Query 'Per DM CLR: The Con Med start date is prior to the start date of the MH-ADHD-01 JUN 2019. Please review and reconcile the Con Med and MH start dates as appropriate. ' answered with 'data entry error' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:41:02
User entered '01 Jun 2019' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:40:53
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the MH-ADHD-01 JUN 2019. Please review and reconcile the Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:25:20
User entered '01 Jan 2019'	(b) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 22:25:09

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:28:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:28:58
Data point term sent to Coder	System	01 Oct 2020 22:28:07
User entered 'Flu vaccine'	(b) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Oct 2020 22:27:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 22:27:34
User entered 'Prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 22:27:34
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 22:27:20
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'UNK'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'mL (mL)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'once (ONCE)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '09 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '09 Sep 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User entered empty.	System	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User entered empty.	System	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:54:02
User entered empty.	System	01 Oct 2020 22:27:20

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:55:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:55:36
Data point term sent to Coder	System	14 Oct 2020 13:41:00
User entered 'zoloft'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'antidepressant'	(b) (4) Jessica McDowell (b) (4)	14 Oct 2020 13:40:50

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'oral'	(b) (4) Jessica McDowell (b) (4)	14 Oct 2020 13:40:50

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'mg (mg)'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'once daily (QD)'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'Oral (ORAL)'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered '14 Oct 2020'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	14 Oct 2020 13:40:50
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Oct 2020 13:40:50

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Oct 2020 13:40:50

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 13:40:50

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Nov 2020 19:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 19:37:46
Data point term sent to Coder	System	16 Nov 2020 19:36:36
User entered 'klonopin'	Jessica McDowell (b) (4) (b) (4)	16 Nov 2020 19:36:27

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	25 Jan 2021 05:49:47
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE for Anxiety will be updated ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	21 Jan 2021 17:42:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:27:22
User entered 'anxiety'	Jessica McDowell (b) (4) (b) (4)	16 Nov 2020 19:36:27

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'I'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'mg (mg)'	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'twice daily (BID)'	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'Oral (ORAL)'	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered '9 Nov 2020'	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered '0'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	16 Nov 2020 19:36:27
	(b) (4)	

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 19:36:27

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:36:27

US3572027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 19:36:27

US3572027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:59:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	02 Apr 2021 04:45:25
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	29 Aug 2020 22:23:22