

US3272060 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:23:20

All time stamps listed in this document are displayed in GMT

US3272060

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Participant ID

US3272060

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

US3272060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

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

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3272060

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Date of Birth (MMM yyyy)	(b) (6)	1998
Age		22
Age Units		YEARS
Age (Derived)		22
Sex	Female	<input type="radio"/>
	Male	<input checked="" type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input checked="" type="radio"/>
	Not Reported	<input type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		True
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

US3272060

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Date of Informed Consent (<i>dd MMM yyyy</i>)	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3272060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3272060

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Were any significant conditions reported?

Yes ☒

No ☐

US3272060

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3272060

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3272060

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:25
Height (xxx.x)	178 cm
Weight (xxx.x)	86.1 kg
BMI (xxx.x)	27.17460 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)	

US3272060

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3272060

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

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

GROCERY STORE,
RESTAURANTS, MALL

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3272060

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

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)	True
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	

US3272060

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3272060

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101639

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 ☒

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Height	ND - Not Done
Weight	ND - Not Done

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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)	06 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:55
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	84 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)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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)	06 AUG 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 12:33
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3272060

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 12:01 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 12:01

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

US3272060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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

Collection date (dd MMM yyyy)	06 AUG 2020
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Collection time (00:00-23:59)	11:10 (24 HR)
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Collection date and time (derived)	06 AUG 2020 11:10
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US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:08	6 AUG 2020 11:08
Nasopharyngeal Swab 2	No		

US3272060

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 12:50

PC Open Date & Time

06 AUG 2020 12:21

PC Close Date & Time

06 AUG 2020 14:51

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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 98.5 °F

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

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

PC Time Stamp	06 AUG 2020 18:37
PC Open Date & Time	06 AUG 2020 15:46
PC Close Date & Time	07 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

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	98.4 °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	07 AUG 2020 19:44
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

08 AUG 2020 19:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

09 AUG 2020 19:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

10 AUG 2020 19:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:46

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

97.8 °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

12 AUG 2020 20:29

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

06 AUG 2020 12:50

PC Open Date & Time

06 AUG 2020 12:21

PC Close Date & Time

06 AUG 2020 14:51

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

06 AUG 2020 18:37

PC Open Date & Time

06 AUG 2020 15:46

PC Close Date & Time

07 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

07 AUG 2020 19:45

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 19:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

10 AUG 2020 19:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

11 AUG 2020 18:46

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

12 AUG 2020 20:30

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 12:51
PC Open Date & Time	06 AUG 2020 12:21
PC Close Date & Time	06 AUG 2020 14:51

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 18:38
PC Open Date & Time	06 AUG 2020 15:46
PC Close Date & Time	07 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

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 ☒

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:47
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

EAB) (1725)

45 of 1877

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

47 of 1877

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:25
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

49 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:01
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

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 ☒

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:47
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

53 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:30
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3272060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

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

Visit date (dd MMM yyyy)	03 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

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)	03 SEP 2020
Time of assessment (00:00-23:59)	09:58 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 09:58
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

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)	03 SEP 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 11:30
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3272060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 10:54 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 10:54

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

US3272060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

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

Collection date (dd MMM yyyy)	03 SEP 2020
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Collection time (00:00-23:59)	10:09 (24 HR)
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Collection date and time (derived)	03 SEP 2020 10:09
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US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:02	03 SEP 2020 10:02
Nasopharyngeal Swab 2	No		

US3272060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:20

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 11:40

PC Open Date & Time

03 SEP 2020 11:14

PC Close Date & Time

03 SEP 2020 13:44

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	03 SEP 2020 18:58
PC Open Date & Time	03 SEP 2020 14:39
PC Close Date & Time	04 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 18:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:33

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

06 SEP 2020 18:15

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 18:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

08 SEP 2020 18:09

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

97.1 °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

09 SEP 2020 17:49

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 11:40

PC Open Date & Time

03 SEP 2020 11:14

PC Close Date & Time

03 SEP 2020 13:44

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

03 SEP 2020 18:58

PC Open Date & Time

03 SEP 2020 14:39

PC Close Date & Time

04 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

04 SEP 2020 18:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 18:33

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

07 SEP 2020 18:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

08 SEP 2020 18:09

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

09 SEP 2020 17:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 11:41
PC Open Date & Time	03 SEP 2020 11:14
PC Close Date & Time	03 SEP 2020 13:44

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:58
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PC Open Date & Time	03 SEP 2020 14:39
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PC Close Date & Time	04 SEP 2020 11:59
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US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

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 ☒

PRODUCTION RELEASE (v12.003

89 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:44
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

91 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:34
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

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 ☒

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:16
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

95 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:55
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:09
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

99 of 1877

EAB) (1725)

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 17:50
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

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

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

Folder OID	VISIT3
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US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 14:19
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3272060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

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

Collection date (dd MMM yyyy)	01 OCT 2020
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Collection time (00:00-23:59)	14:16 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	01 OCT 2020 14:16
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US3272060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 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	06 OCT 2020 14:25:13
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 13:31:18

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 09:21:27

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 06:49:20

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 07:45:44

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 19:35:24

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 06:33:08

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 15:29:22

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

Patient Cloud Open Date & Time	05 DEC 2020 00:01
--	-------------------

Patient Cloud Close Date & Time	09 DEC 2020 23:59
---	-------------------

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 16:33:49

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 14:17:15

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 14:22:32

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

10 JAN 2021 15:34:12

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 03:02:41

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 12:00:13

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 12:00:50

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

06 FEB 2021 11:57:03

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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	13 FEB 2021 07:28:58
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

20 FEB 2021 15:38:19

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

27 FEB 2021 09:22:53

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 01:15:22

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

15 MAR 2021 12:30:29

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 08:58:56

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

29 MAR 2021 08:31:19

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:53:39

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 09:13:38

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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°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 ☐

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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="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"/>

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3272060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:23:20

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		27 FEB 2021 09:23:07

US3272060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

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

Visit date (dd MMM yyyy)	26 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3272060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3272060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

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

Collection date (dd MMM yyyy)	26 FEB 2021
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Collection time (00:00-23:59)	13:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 FEB 2021 13:27
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US3272060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:21

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272060

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272060

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272060

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:23:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3272060

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3272060

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3272060

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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

Collection date (dd MMM yyyy)	15 JAN 2021
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Collection time (00:00-23:59)	10:11 (24 HR)
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Collection date and time (derived)	15 JAN 2021 10:11
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US3272060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

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

Collection date (dd MMM yyyy)	15 JAN 2021
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Collection time (00:00 - 23:59)	10:13
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Collection Date and Time (derived)	15 JAN 2021 10:13
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US3272060

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

AEID	
Adverse event	WORSENING OF DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 FEB 2021
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 type="radio"/> Grade 3/Severe <input checked="" 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 1877

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

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 type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

AEID	USA-US070-2021-MRNA-1273-P30 1000007
Adverse event	SUICIDE ATTEMPT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

326 of 1877

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

COMPLAINS OF RECENT
WORSENING OF DEPRESSION
CULMINATING IN A SUICIDE
ATTEMPT 21FEB2021. SUBJECT
HAS HISTORY OF MODERATE
DEPRESSION AND ADHD AND
WAS STABLE ON HIS MEDICAL
REGIMEN. HAD RECENT LOSS
OF EMPLOYMENT THAT UPSET
HIS ROUTINE AND WORSENERD
SYMPTOMS. SUBJECT (b) (6)

WAS NOT HOSPITALIZED OR
TAKEN INTO CUSTODY, HIS
MOTHER TOOK HIM TO HIS
DOCTOR FOR EVALUATION
WHERE HE INITIATED LITHIUM
150 MG PO DAILY. IS
CURRENTLY STABLE WITH NO
SUICIDAL OR SELF-HARM
IDEATION, HAS WEEKLY
APPOINTMENTS WITH
PROVIDER.

MEDICAL RECORD RELATES
INCIDENT AS SELF-HARM
ATTEMPT, NOT A SUICIDE
ATTEMPT. DIAGNOSES OF
ASPERGER'S SYNDROME AND
MODERATE, RECURRENT,
MAJOR DEPRESSIVE DISORDER.
FOLLOWING UP WITH
THERAPIST WEEKLY AND
WITH PSYCHIATRY MONTHLY.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

AEID	
Adverse event	ASPERGER'S SYNDROME
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 FEB 2021
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 checked="" type="radio"/> Grade 2/Moderate <input 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	

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 14:51:55

Generated On: 09 Jun 2021 16:23:20

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

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

Yes ☒

No ☐

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

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication ARIPIRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVE DISORDER

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

332 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 2010	
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"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication STRATTERA

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 80

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 2010	
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"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication LITHIUM CARBONATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING DEPRESSION

Dose per administration 150

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication FLUXOXAMINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 2010	
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"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication BUSPAR

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 2010	
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"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 0.2

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 2010	
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"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication CLOZARIL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 2010	
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"/>

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 3

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 1877

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

	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 UNK 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"/>

US3272060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 14:51:56

Generated On: 09 Jun 2021 16:23:20

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3272060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:23:20

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

US3272060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:23:20

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 ☐

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

SAEID	USA-US070-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

SAEID	USA-US070-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/MAR/2021 13:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

SAEID	USA-US070-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 17:07:19

Generated On: 09 Jun 2021 16:23:20

SAEID	USA-US070-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/MAR/2021 13:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3272060 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272060

Form: Participant Creation

Generated On: 09 Jun 2021 16:23:20

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:06:34
User entered 'US3272060'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:22

US3272060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:16:32

US3272060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:23

US3272060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Aug 2020 22:16:32

US3272060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'SCRN'	System	07 Aug 2020 22:16:32

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered (b) (6)1998'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:24

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:17:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 22:17:41
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	07 Aug 2020 22:17:41
User entered '22' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 22:17:41
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 17:18:10
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	06 Aug 2020 17:18:10
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'YEARS'	System	07 Aug 2020 22:17:41
User entered empty.	System	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '22'	System	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Male (M)'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Aug 2020 22:17:41
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '1' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 22:17:41
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 17:54:53
User entered '1'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 17:18:10

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '06 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'Aug 2020'	System	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '2020'	System	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 17:18:47

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

If Yes, [previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:23

US3272060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '1'	System	06 Aug 2020 17:37:18

US3272060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Ashley Bell (b) (4)	06 Aug 2020 17:37:18

US3272060

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:23:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:25:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:27:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:27:19
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 22:26:10
User entered 'Attention Deficit Hyperactivity Disorder'	(b) (4), (b) (6)	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'un UNK 2002'	(b) (4), (b) (6)	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'Jan 2002'	System	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '2002'	System	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered empty.	System	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered empty.	System	07 Aug 2020 22:26:05

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:27:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:27:20
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 22:27:11
User entered 'Depression'	(b) (4), (b) (6)	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:03:33
User entered 'un UNK 2019'	(b) (4), (b) (6)	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'Jan 2010'	System	22 Sep 2020 00:03:33
User entered 'Jan 2019'	System	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '2010'	System	22 Sep 2020 00:03:33
User entered '2019'	System	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered empty.	System	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered empty.	System	07 Aug 2020 22:26:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:21:34
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 15:56:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:05:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered 'Yes (Y)'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '06 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '06 Aug 2020'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '10:25' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '10:25'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '06 Aug 2020 10:25'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered '06 Aug 2020 10:25'	System	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '178' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '178' cm		07 Aug 2020 22:45:31
DataPoint set to visible.	System	06 Aug 2020 17:37:18

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '86.1' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '86.1' kg	(b) (4), (b) (6)	07 Aug 2020 22:45:31
DataPoint set to visible.	System	06 Aug 2020 17:37:18

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered '27.17460'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered '27.2'	System	07 Aug 2020 22:45:31
DataPoint set to visible.	System	06 Aug 2020 17:37:18

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'kg/m2'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered 'kg/m2'	System	07 Aug 2020 22:45:31
DataPoint set to visible.	System	06 Aug 2020 17:37:18

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:21:37
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 15:56:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:06:30
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:06:30
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:43:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:35:57

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	(b) (4), (b) (6)	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered 'Other (Other)'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered 'Temporal'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '84'	(b) (4), (b) (6)	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'bpm'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered 'bpm'	System	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '18'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'breaths/min'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered 'breaths/min'	System	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '118'		07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'mmHg'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered 'mmHg'	System	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 15:56:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:43:10
User entered '70'	(b) (4), (b) (6)	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User entered 'mmHg'	System	25 Sep 2020 15:56:46
User entered empty.	System	15 Sep 2020 23:43:10
User entered 'mmHg'	System	07 Aug 2020 22:45:31

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27

US3272060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27

US3272060

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:45:59

US3272060

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:20:05
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 16:01:14
User entered '06 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:45:59

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 17:55:32
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 14:09:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 14:09:59
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	15 Aug 2020 14:09:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:46:19
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'grocery store, restaurants, mall' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 17:55:32
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'I'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:18:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:46:19

US3272060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 17:19:14

US3272060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 17:19:14

US3272060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Aug 2020 17:19:14

US3272060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'VISIT1'	System	06 Aug 2020 17:19:14

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:34

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:33:59
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:33:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 16:34:34
User entered '101639' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:34

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:34:34

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 13:37:07

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 13:37:07

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 13:37:07

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 13:37:07

US3272060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 13:37:07

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:30:47
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:07:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:07:08
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:12:49
User entered '178' cm	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:30:52
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:07:08
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:12:58
User entered '86.1' kg	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:30:47
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:07:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:07:08
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:12:49
User entered '178' cm	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:30:52
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:07:08
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:12:58
User entered '86.1' kg	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User accepted default value 'Pre-Dose (PREDOSE)'		07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10:55'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered '06 Aug 2020 10:55'	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '37.1' C	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Other (Other)'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Temporal'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:42:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:42:28
User entered '84' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:42:28
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:09
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'bpm'	System	07 Aug 2020 13:42:28
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:42:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:42:28
User entered '18' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:42:28
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:09
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'breaths/min'	System	07 Aug 2020 13:42:28
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:42:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:42:28
User entered '118' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:42:28
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:09
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'mmHg'	System	07 Aug 2020 13:42:28
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:42:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:42:28
User entered '70' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:42:28
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:09
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'mmHg'	System	07 Aug 2020 13:42:28
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:30:47
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:07:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:07:08
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:12:49
User entered '178' cm	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:30:52
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:07:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:07:08
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:12:58
User entered '86.1' kg	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User accepted default value 'Post-Dose (POSTDOSE)'		07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 13:39:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 13:39:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Aug 2020 13:39:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 13:39:09
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:47
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Aug 2020 13:39:47
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 13:25:46
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'confirm correct ' (Site from System).	Ashley Bell (b) (4)	15 Aug 2020 13:57:38
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 13:39:47
User closed query 'Data is required. Please provide.' System (Site from System).		07 Aug 2020 13:39:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:39:47
User entered '12:33' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Aug 2020 13:39:47
User opened query 'Data is required. Please provide.' System (Site from System).		07 Aug 2020 13:39:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered '06 Aug 2020 12:33'	System	07 Aug 2020 13:39:47
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '36.3' C	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Other (Other)'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Temporal'	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:43:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:43:08
User entered '77' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:43:08
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'bpm'	System	07 Aug 2020 13:43:08
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:43:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:43:08
User entered '14' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:43:08
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'breaths/min'	System	07 Aug 2020 13:43:08
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:43:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:43:08
User entered '112' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:43:08
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'mmHg'	System	07 Aug 2020 13:43:08
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:43:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 13:43:08
User entered '78' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 13:43:08
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 13:39:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'mmHg'	System	07 Aug 2020 13:43:08
User entered empty.	System	07 Aug 2020 13:39:09

US3272060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 13:49:15

US3272060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 13:49:15

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Ashley Bell (b) (4)	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '06 Aug 2020'	Ashley Bell (b) (4)	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '12:01'	Ashley Bell (b) (4)	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered '06 Aug 2020 12:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Left Arm (LEFT ARM)'	Ashley Bell (b) (4)	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'ONCE'	System	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 17:37:49

US3272060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:08:27

US3272060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:08:27

US3272060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '11:10'	(b) (4), (b) (6)	07 Aug 2020 14:08:27

US3272060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered '06 Aug 2020 11:10'	System	07 Aug 2020 14:08:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '11:08'	(b) (4), (b) (6)	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered '6 Aug 2020 11:08'	System	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered empty.	System	28 Aug 2020 18:59:27

US3272060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:59:31

US3272060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:19:32
User entered 'I'	System	28 Aug 2020 18:59:31

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'fd399571-51bc-41f3-8383-73e3db3f1314'	System	06 Aug 2020 17:50:33
User entered 'Yes (Y)'	System	06 Aug 2020 17:50:33

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:16', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'fd399571-51bc-41f3-8383-73e3db3f1314'	System	06 Aug 2020 17:50:33
User entered '98.2'	System	06 Aug 2020 17:50:33

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:20', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'fd399571-51bc-41f3-8383-73e3db3f1314'	System	06 Aug 2020 17:50:33
User entered 'No (N)'	System	06 Aug 2020 17:50:33

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:24', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'fd399571-51bc-41f3-8383-73e3db3f1314'	System	06 Aug 2020 17:50:33
User entered '06 Aug 2020 12:50'	System	06 Aug 2020 17:50:33

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 12:21'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 14:51'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:36:48', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b7c8a3e3-b067-42c0-8a3f-8c32d02ff616'	System	06 Aug 2020 23:37:10
User entered 'Yes (Y)'	System	06 Aug 2020 23:37:10

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:36:52', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b7c8a3e3-b067-42c0-8a3f-8c32d02ff616'	System	06 Aug 2020 23:37:10
User entered '98.5'	System	06 Aug 2020 23:37:10

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:05', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b7c8a3e3-b067-42c0-8a3f-8c32d02ff616'	System	06 Aug 2020 23:37:10
User entered 'No (N)'	System	06 Aug 2020 23:37:10

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b7c8a3e3-b067-42c0-8a3f-8c32d02ff616'	System	06 Aug 2020 23:37:10
User entered '06 Aug 2020 18:37'	System	06 Aug 2020 23:37:10

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 15:46'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 2'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:44:07', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '32c4cde4-9ed9-4a3c-94b4-b150ab262e3e'	System	08 Aug 2020 00:44:57
User entered 'Yes (Y)'	System	08 Aug 2020 00:44:57

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:44:29', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '32c4cde4-9ed9-4a3c-94b4-b150ab262e3e'	System	08 Aug 2020 00:44:57
User entered '98.4'	System	08 Aug 2020 00:44:57

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:44:40', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '32c4cde4-9ed9-4a3c-94b4-b150ab262e3e'	System	08 Aug 2020 00:44:57
User entered 'Yes (Y)'	System	08 Aug 2020 00:44:57

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
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 'Patient called. Stated he marked yes by mistake' (Site from System).	(b) (4)	01 Sep 2020 17:56:45
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).	Kayla Flege (b) (4)	15 Aug 2020 14:05:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:44:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '32c4cde4-9ed9-4a3c-94b4-b150ab262e3e'	(b) (4)	
User entered '1'	System	08 Aug 2020 00:44:57
	System	08 Aug 2020 00:44:57
	System	08 Aug 2020 00:44:57

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:44:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '32c4cde4-9ed9-4a3c-94b4-b150ab262e3e' User entered '0'	System	08 Aug 2020 00:44:57
	System	08 Aug 2020 00:44:57

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:44:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '32c4cde4-9ed9-4a3c-94b4-b150ab262e3e'	System	08 Aug 2020 00:44:57
User entered '07 Aug 2020 19:44'	System	08 Aug 2020 00:44:57

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 3'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:03:37', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f3b29e8c-01a6-4953-a604-b1878e04e110'	System	09 Aug 2020 00:03:49
User entered 'Yes (Y)'	System	09 Aug 2020 00:03:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:03:41', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f3b29e8c-01a6-4953-a604-b1878e04e110'	System	09 Aug 2020 00:03:49
User entered '98.4'	System	09 Aug 2020 00:03:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:03:45', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f3b29e8c-01a6-4953-a604-b1878e04e110'	System	09 Aug 2020 00:03:49
User entered 'No (N)'	System	09 Aug 2020 00:03:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:03:47', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f3b29e8c-01a6-4953-a604-b1878e04e110'	System	09 Aug 2020 00:03:49
User entered '08 Aug 2020 19:03'	System	09 Aug 2020 00:03:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 4'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:26', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'dbc93470-5253-4530-b217-ec808f8ec6d'	System	10 Aug 2020 00:24:37
User entered 'Yes (Y)'	System	10 Aug 2020 00:24:37

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:30', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'dbc93470-5253-4530-b217-ece808f8ec6d'	System	10 Aug 2020 00:24:37
User entered '97.8'	System	10 Aug 2020 00:24:37

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'dbc93470-5253-4530-b217-ece808f8ec6d'	System	10 Aug 2020 00:24:37
User entered 'No (N)'	System	10 Aug 2020 00:24:37

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:35', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'dbc93470-5253-4530-b217-ece808f8ec6d'	System	10 Aug 2020 00:24:37
User entered '09 Aug 2020 19:24'	System	10 Aug 2020 00:24:37

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 5'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab6b3e14-9489-47e4-ab87-1828ba6ad69a'	System	11 Aug 2020 00:01:18
User entered 'Yes (Y)'	System	11 Aug 2020 00:01:18

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:10', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab6b3e14-9489-47e4-ab87-1828ba6ad69a'	System	11 Aug 2020 00:01:18
User entered '98.4'	System	11 Aug 2020 00:01:18

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab6b3e14-9489-47e4-ab87-1828ba6ad69a'	System	11 Aug 2020 00:01:18
User entered 'No (N)'	System	11 Aug 2020 00:01:18

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab6b3e14-9489-47e4-ab87-1828ba6ad69a'	System	11 Aug 2020 00:01:18
User entered '10 Aug 2020 19:01'	System	11 Aug 2020 00:01:18

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 6'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'a6f2337d-b6f5-4cd0-bac8-f6360d2e2ab6'	System	11 Aug 2020 23:46:30
User entered 'Yes (Y)'	System	11 Aug 2020 23:46:30

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:17', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'a6f2337d-b6f5-4cd0-bac8-f6360d2e2ab6'	System	11 Aug 2020 23:46:30
User entered '98.0'	System	11 Aug 2020 23:46:30

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:20', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'a6f2337d-b6f5-4cd0-bac8-f6360d2e2ab6'	System	11 Aug 2020 23:46:30
User entered 'No (N)'	System	11 Aug 2020 23:46:30

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:27', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'a6f2337d-b6f5-4cd0-bac8-f6360d2e2ab6'	System	11 Aug 2020 23:46:30
User entered '11 Aug 2020 18:46'	System	11 Aug 2020 23:46:30

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 7'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:29:32', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '55065da5-68a2-436b-b2f2-77bfba06e213'	System	13 Aug 2020 01:29:52
User entered 'Yes (Y)'	System	13 Aug 2020 01:29:52

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:29:41', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '55065da5-68a2-436b-b2f2-77bfba06e213'	System	13 Aug 2020 01:29:52
User entered '97.8'	System	13 Aug 2020 01:29:52

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:29:44', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '55065da5-68a2-436b-b2f2-77bfba06e213'	System	13 Aug 2020 01:29:52
User entered 'No (N)'	System	13 Aug 2020 01:29:52

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:29:46', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '55065da5-68a2-436b-b2f2-77bfba06e213'	System	13 Aug 2020 01:29:52
User entered '12 Aug 2020 20:29'	System	13 Aug 2020 01:29:52

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '584d779b-6d20-48b3-906e-f2d6eb3f94e4'	System	06 Aug 2020 17:50:51
User entered 'None (1)'	System	06 Aug 2020 17:50:51

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:39', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '584d779b-6d20-48b3-906e-f2d6eb3f94e4'	System	06 Aug 2020 17:50:51
User entered 'No (N)'	System	06 Aug 2020 17:50:51

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '584d779b-6d20-48b3-906e-f2d6eb3f94e4'	System	06 Aug 2020 17:50:51
User entered 'No (N)'	System	06 Aug 2020 17:50:51

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:46', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '584d779b-6d20-48b3-906e-f2d6eb3f94e4'	System	06 Aug 2020 17:50:51
User entered 'None (1)'	System	06 Aug 2020 17:50:51

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:48', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '584d779b-6d20-48b3-906e-f2d6eb3f94e4'	System	06 Aug 2020 17:50:51
User entered '06 Aug 2020 12:50'	System	06 Aug 2020 17:50:51

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 12:21'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 14:51'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:14', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '793472fa-f093-4a28-af65-d37bce0bba3d'	System	06 Aug 2020 23:37:56
User entered 'None (1)'	System	06 Aug 2020 23:37:56

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:23', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '793472fa-f093-4a28-af65-d37bce0bba3d'	System	06 Aug 2020 23:37:56
User entered 'No (N)'	System	06 Aug 2020 23:37:56

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:32', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '793472fa-f093-4a28-af65-d37bce0bba3d'	System	06 Aug 2020 23:37:56
User entered 'No (N)'	System	06 Aug 2020 23:37:56

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:51', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '793472fa-f093-4a28-af65-d37bce0bba3d'	System	06 Aug 2020 23:37:56
User entered 'None (1)'	System	06 Aug 2020 23:37:56

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:37:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '793472fa-f093-4a28-af65-d37bce0bba3d'	System	06 Aug 2020 23:37:56
User entered '06 Aug 2020 18:37'	System	06 Aug 2020 23:37:56

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 15:46'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 2'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:45:31', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '92b71267-fcb7-42cf-bc02-bf4151ad44f8'	System	08 Aug 2020 00:46:00
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 00:46:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:45:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '92b71267-fcb7-42cf-bc02-bf4151ad44f8'	System	08 Aug 2020 00:46:00
User entered 'No (N)'	System	08 Aug 2020 00:46:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:45:48', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '92b71267-fcb7-42cf-bc02-bf4151ad44f8'	System	08 Aug 2020 00:46:00
User entered 'No (N)'	System	08 Aug 2020 00:46:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:45:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '92b71267-fcb7-42cf-bc02-bf4151ad44f8'	System	08 Aug 2020 00:46:00
User entered 'None (1)'	System	08 Aug 2020 00:46:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:45:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '92b71267-fcb7-42cf-bc02-bf4151ad44f8'	System	08 Aug 2020 00:46:00
User entered '07 Aug 2020 19:45'	System	08 Aug 2020 00:46:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 3'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:03:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e0eb959c-413d-4b0f-b107-1effe65eb9d9'	System	09 Aug 2020 00:04:18
User entered 'None (1)'	System	09 Aug 2020 00:04:18

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:05', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e0eb959c-413d-4b0f-b107-1effe65eb9d9'	System	09 Aug 2020 00:04:18
User entered 'No (N)'	System	09 Aug 2020 00:04:18

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e0eb959c-413d-4b0f-b107-1effe65eb9d9'	System	09 Aug 2020 00:04:18
User entered 'No (N)'	System	09 Aug 2020 00:04:18

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e0eb959c-413d-4b0f-b107-1effe65eb9d9'	System	09 Aug 2020 00:04:18
User entered 'None (1)'	System	09 Aug 2020 00:04:18

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:16', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e0eb959c-413d-4b0f-b107-1effe65eb9d9'	System	09 Aug 2020 00:04:18
User entered '08 Aug 2020 19:04'	System	09 Aug 2020 00:04:18

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 4'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:40', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95554b1e-13f8-45b4-b982-b64a6f3915c8'	System	10 Aug 2020 00:25:00
User entered 'None (1)'	System	10 Aug 2020 00:25:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:48', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95554b1e-13f8-45b4-b982-b64a6f3915c8'	System	10 Aug 2020 00:25:00
User entered 'No (N)'	System	10 Aug 2020 00:25:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95554b1e-13f8-45b4-b982-b64a6f3915c8'	System	10 Aug 2020 00:25:00
User entered 'No (N)'	System	10 Aug 2020 00:25:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95554b1e-13f8-45b4-b982-b64a6f3915c8'	System	10 Aug 2020 00:25:00
User entered 'None (1)'	System	10 Aug 2020 00:25:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:24:58', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95554b1e-13f8-45b4-b982-b64a6f3915c8'	System	10 Aug 2020 00:25:00
User entered '09 Aug 2020 19:24'	System	10 Aug 2020 00:25:00

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 5'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:35', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88eced07-1f47-40b7-bf3b-ba6fcfd9cddc'	System	11 Aug 2020 00:01:58
User entered 'None (1)'	System	11 Aug 2020 00:01:58

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88eced07-1f47-40b7-bf3b-ba6fcfd9cddc'	System	11 Aug 2020 00:01:58
User entered 'No (N)'	System	11 Aug 2020 00:01:58

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:48', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88eced07-1f47-40b7-bf3b-ba6fcfd9cddc'	System	11 Aug 2020 00:01:58
User entered 'No (N)'	System	11 Aug 2020 00:01:58

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88eced07-1f47-40b7-bf3b-ba6fcfd9cddc'	System	11 Aug 2020 00:01:58
User entered 'None (1)'	System	11 Aug 2020 00:01:58

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88eced07-1f47-40b7-bf3b-ba6fcfd9cddc'	System	11 Aug 2020 00:01:58
User entered '10 Aug 2020 19:01'	System	11 Aug 2020 00:01:58

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 6'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:32', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '11874da3-f3cb-477c-a828-437d48a2746e'	System	11 Aug 2020 23:47:05
User entered 'None (1)'	System	11 Aug 2020 23:47:05

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:43', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '11874da3-f3cb-477c-a828-437d48a2746e'	System	11 Aug 2020 23:47:05
User entered 'No (N)'	System	11 Aug 2020 23:47:05

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '11874da3-f3cb-477c-a828-437d48a2746e'	System	11 Aug 2020 23:47:05
User entered 'No (N)'	System	11 Aug 2020 23:47:05

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '11874da3-f3cb-477c-a828-437d48a2746e'	System	11 Aug 2020 23:47:05
User entered 'None (1)'	System	11 Aug 2020 23:47:05

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:46:58', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '11874da3-f3cb-477c-a828-437d48a2746e'	System	11 Aug 2020 23:47:05
User entered '11 Aug 2020 18:46'	System	11 Aug 2020 23:47:05

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 7'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:29:59', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '72a474a4-0a3e-4891-809e-b40d8957104e'	System	13 Aug 2020 01:30:29
User entered 'None (1)'	System	13 Aug 2020 01:30:29

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:03', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '72a474a4-0a3e-4891-809e-b40d8957104e'	System	13 Aug 2020 01:30:29
User entered 'No (N)'	System	13 Aug 2020 01:30:29

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:07', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '72a474a4-0a3e-4891-809e-b40d8957104e'	System	13 Aug 2020 01:30:29
User entered 'No (N)'	System	13 Aug 2020 01:30:29

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:23', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '72a474a4-0a3e-4891-809e-b40d8957104e'	System	13 Aug 2020 01:30:29
User entered 'None (1)'	System	13 Aug 2020 01:30:29

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:24', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '72a474a4-0a3e-4891-809e-b40d8957104e'	System	13 Aug 2020 01:30:29
User entered '12 Aug 2020 20:30'	System	13 Aug 2020 01:30:29

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'None (0)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:50:58', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'None (0)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:51:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'None (0)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:51:03', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'None (0)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:51:05', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'None (0)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:51:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'None (0)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:51:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered 'No (N)'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T12:51:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1d6a6368-ef7a-4d2d-9888-76d617dabb37'	System	06 Aug 2020 17:51:21
User entered '06 Aug 2020 12:51'	System	06 Aug 2020 17:51:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 12:21'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 14:51'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:10', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'None (0)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'None (0)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:26', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'None (0)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:28', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'None (0)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:30', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'None (0)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'None (0)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:38', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered 'No (N)'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-06T18:38:41', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4a0b4364-8080-4ba5-9742-4ade185567ad'	System	06 Aug 2020 23:38:43
User entered '06 Aug 2020 18:38'	System	06 Aug 2020 23:38:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Aug 2020 15:46'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 2'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:46:46', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'None (0)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:46:52', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'None (0)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:47:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'None (0)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:47:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'None (0)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:47:07', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'None (0)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:47:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'None (0)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:47:12', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered 'No (N)'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-07T19:47:14', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '65860b45-ac79-495d-8021-a612b762a910'	System	08 Aug 2020 00:47:17
User entered '07 Aug 2020 19:47'	System	08 Aug 2020 00:47:17

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 3'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:25', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'None (0)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:27', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'None (0)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:29', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'None (0)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:32', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'None (0)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:34', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'None (0)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'None (0)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:39', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered 'No (N)'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-08T19:04:41', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1cb29ffe-ea11-4a41-891b-a33edaca3f78'	System	09 Aug 2020 00:04:43
User entered '08 Aug 2020 19:04'	System	09 Aug 2020 00:04:43

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 4'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'None (0)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'None (0)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'None (0)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'None (0)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'None (0)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'None (0)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered 'No (N)'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-09T19:25:17', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '089ee7b4-db69-49cd-8f3f-038072af3a7e'	System	10 Aug 2020 00:25:48
User entered '09 Aug 2020 19:25'	System	10 Aug 2020 00:25:48

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 5'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:19', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'None (0)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'None (0)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:22', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'None (0)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:23', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'None (0)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:25', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'None (0)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:26', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'None (0)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:29', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered 'No (N)'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-10T19:01:31', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ab40a4fd-e64b-423f-9da9-1908be16f051'	System	11 Aug 2020 00:01:37
User entered '10 Aug 2020 19:01'	System	11 Aug 2020 00:01:37

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 6'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:05', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'None (0)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'None (0)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'None (0)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'None (0)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'None (0)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'None (0)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:16', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered 'No (N)'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-11T18:47:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '53e6209c-4e55-4f5e-b72f-55b1a7e521ce'	System	11 Aug 2020 23:47:21
User entered '11 Aug 2020 18:47'	System	11 Aug 2020 23:47:21

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 7'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:28', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'None (0)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:30', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'None (0)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:31', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'None (0)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'None (0)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:34', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'None (0)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'None (0)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:43', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered 'No (N)'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-08-12T20:30:50', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8343f6ab-0bc1-45aa-a9dd-ed956d70d3fb'	System	13 Aug 2020 01:30:56
User entered '12 Aug 2020 20:30'	System	13 Aug 2020 01:30:56

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:37:49

US3272060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:00:08

US3272060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '13 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:00:08

US3272060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 19:00:08

US3272060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:00:08

US3272060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:00:13

US3272060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:19
User entered 'I'	System	28 Aug 2020 19:00:13

US3272060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:00:31

US3272060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '20 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:00:31

US3272060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 19:00:31

US3272060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:00:31

US3272060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:00:37

US3272060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:05
User entered 'I'	System	28 Aug 2020 19:00:37

US3272060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:37:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:00:49

US3272060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:37:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:00:49

US3272060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:37:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 19:00:49

US3272060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:37:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:00:49

US3272060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:37:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:00:54

US3272060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:37:51
User entered 'I'	System	28 Aug 2020 19:00:54

US3272060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Ashley Bell (b) (4)	03 Sep 2020 16:01:14

US3272060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	Ashley Bell (b) (4)	03 Sep 2020 16:01:14

US3272060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	03 Sep 2020 16:01:14

US3272060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'VISIT2'	System	03 Sep 2020 16:01:14

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User accepted default value 'Pre-Dose (PREDOSE)'		03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '09:58'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered '03 Sep 2020 09:58'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '36.8' C	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '91'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'bpm'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '16'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'breaths/min'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '134'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'mmHg'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '77'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'mmHg'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User accepted default value 'Post-Dose (POSTDOSE)'		03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '11:30'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered '03 Sep 2020 11:30'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '36.5' C	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '86'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'bpm'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '12'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'breaths/min'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '117'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'mmHg'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '81'	(b) (4), (b) (6)	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'mmHg'	System	03 Sep 2020 16:52:24

US3272060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:52:37

US3272060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 16:52:37

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Ashley Bell (b) (4)	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	Ashley Bell (b) (4)	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10:54'	Ashley Bell (b) (4)	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered '03 Sep 2020 10:54'	System	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Left Arm (LEFT ARM)'	Ashley Bell (b) (4)	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'ONCE'	System	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 16:01:39

US3272060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:53:34

US3272060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 16:53:34

US3272060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10:09'	(b) (4), (b) (6)	03 Sep 2020 16:53:34

US3272060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered '03 Sep 2020 10:09'	System	03 Sep 2020 16:53:34

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10:02'	(b) (4), (b) (6)	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered '03 Sep 2020 10:02'	System	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered empty.	System	03 Sep 2020 16:53:57

US3272060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 16:54:04

US3272060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:40
User entered 'I'	System	03 Sep 2020 16:54:04

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '447b0e87-59b2-4283-b5b9-326b18f81d93'	System	03 Sep 2020 16:40:31
User entered 'Yes (Y)'	System	03 Sep 2020 16:40:31

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:22', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '447b0e87-59b2-4283-b5b9-326b18f81d93'	System	03 Sep 2020 16:40:31
User entered '97.7'	System	03 Sep 2020 16:40:31

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:26', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '447b0e87-59b2-4283-b5b9-326b18f81d93'	System	03 Sep 2020 16:40:31
User entered 'No (N)'	System	03 Sep 2020 16:40:31

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:28', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '447b0e87-59b2-4283-b5b9-326b18f81d93'	System	03 Sep 2020 16:40:31
User entered '03 Sep 2020 11:40'	System	03 Sep 2020 16:40:31

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 11:14'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 13:44'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '666c1c54-83e8-48e1-9de2-178b33e7b568'	System	03 Sep 2020 23:58:27
User entered 'Yes (Y)'	System	03 Sep 2020 23:58:27

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '666c1c54-83e8-48e1-9de2-178b33e7b568' User entered '97.3'	System	03 Sep 2020 23:58:27
	System	03 Sep 2020 23:58:27

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '666c1c54-83e8-48e1-9de2-178b33e7b568'	System	03 Sep 2020 23:58:27
User entered 'No (N)'	System	03 Sep 2020 23:58:27

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '666c1c54-83e8-48e1-9de2-178b33e7b568'	System	03 Sep 2020 23:58:27
User entered '03 Sep 2020 18:58'	System	03 Sep 2020 23:58:27

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 2'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:43:43', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '2a923233-a76e-4d2f-b871-31646b837684'	System	04 Sep 2020 23:44:09
User entered 'Yes (Y)'	System	04 Sep 2020 23:44:09

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:43:59', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '2a923233-a76e-4d2f-b871-31646b837684'	System	04 Sep 2020 23:44:09
User entered '98.2'	System	04 Sep 2020 23:44:09

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:01', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '2a923233-a76e-4d2f-b871-31646b837684'	System	04 Sep 2020 23:44:09
User entered 'No (N)'	System	04 Sep 2020 23:44:09

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '2a923233-a76e-4d2f-b871-31646b837684'	System	04 Sep 2020 23:44:09
User entered '04 Sep 2020 18:44'	System	04 Sep 2020 23:44:09

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 3'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:32:47', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '657c991b-929e-4c4f-bfd5-a347317f77c6'	System	05 Sep 2020 23:33:06
User entered 'Yes (Y)'	System	05 Sep 2020 23:33:06

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:32:59', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '657c991b-929e-4c4f-bfd5-a347317f77c6'	System	05 Sep 2020 23:33:06
User entered '98.6'	System	05 Sep 2020 23:33:06

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:01', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '657c991b-929e-4c4f-bfd5-a347317f77c6'	System	05 Sep 2020 23:33:06
User entered 'No (N)'	System	05 Sep 2020 23:33:06

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:03', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '657c991b-929e-4c4f-bfd5-a347317f77c6'	System	05 Sep 2020 23:33:06
User entered '05 Sep 2020 18:33'	System	05 Sep 2020 23:33:06

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 4'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:19', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c0bae05c-743b-463a-9f1b-141fd1d96530'	System	06 Sep 2020 23:15:39
User entered 'Yes (Y)'	System	06 Sep 2020 23:15:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:28', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c0bae05c-743b-463a-9f1b-141fd1d96530'	System	06 Sep 2020 23:15:39
User entered '98.2'	System	06 Sep 2020 23:15:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:31', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c0bae05c-743b-463a-9f1b-141fd1d96530'	System	06 Sep 2020 23:15:39
User entered 'No (N)'	System	06 Sep 2020 23:15:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:34', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c0bae05c-743b-463a-9f1b-141fd1d96530'	System	06 Sep 2020 23:15:39
User entered '06 Sep 2020 18:15'	System	06 Sep 2020 23:15:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 5'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e7168730-d5a2-4106-aada-df88b12b606a'	System	07 Sep 2020 23:54:45
User entered 'Yes (Y)'	System	07 Sep 2020 23:54:45

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e7168730-d5a2-4106-aada-df88b12b606a' User entered '97.7'	System	07 Sep 2020 23:54:45
	System	07 Sep 2020 23:54:45

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:38', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e7168730-d5a2-4106-aada-df88b12b606a'	System	07 Sep 2020 23:54:45
User entered 'No (N)'	System	07 Sep 2020 23:54:45

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:40', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e7168730-d5a2-4106-aada-df88b12b606a'	System	07 Sep 2020 23:54:45
User entered '07 Sep 2020 18:54'	System	07 Sep 2020 23:54:45

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 6'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:08:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '0f24c6b3-4957-4e2f-958d-8f71c01aaeed'	System	08 Sep 2020 23:09:20
User entered 'Yes (Y)'	System	08 Sep 2020 23:09:20

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '0f24c6b3-4957-4e2f-958d-8f71c01aaed'	System	08 Sep 2020 23:09:20
User entered '98.0'	System	08 Sep 2020 23:09:20

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '0f24c6b3-4957-4e2f-958d-8f71c01aaeed'	System	08 Sep 2020 23:09:20
User entered 'No (N)'	System	08 Sep 2020 23:09:20

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:16', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '0f24c6b3-4957-4e2f-958d-8f71c01aaeed'	System	08 Sep 2020 23:09:20
User entered '08 Sep 2020 18:09'	System	08 Sep 2020 23:09:20

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 7'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:49:25', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c61dc95d-113b-49fe-bfa9-cf927513c276'	System	09 Sep 2020 22:49:55
User entered 'Yes (Y)'	System	09 Sep 2020 22:49:55

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:49:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c61dc95d-113b-49fe-bfa9-cf927513c276' User entered '97.1'	System	09 Sep 2020 22:49:55
	System	09 Sep 2020 22:49:55

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:49:46', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c61dc95d-113b-49fe-bfa9-cf927513c276'	System	09 Sep 2020 22:49:55
User entered 'No (N)'	System	09 Sep 2020 22:49:55

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:49:50', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c61dc95d-113b-49fe-bfa9-cf927513c276'	System	09 Sep 2020 22:49:55
User entered '09 Sep 2020 17:49'	System	09 Sep 2020 22:49:55

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '09d1c172-0427-4175-923c-e725031d3d28'	System	03 Sep 2020 16:40:46
User entered 'None (1)'	System	03 Sep 2020 16:40:46

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '09d1c172-0427-4175-923c-e725031d3d28'	System	03 Sep 2020 16:40:46
User entered 'No (N)'	System	03 Sep 2020 16:40:46

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:39', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '09d1c172-0427-4175-923c-e725031d3d28'	System	03 Sep 2020 16:40:46
User entered 'No (N)'	System	03 Sep 2020 16:40:46

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '09d1c172-0427-4175-923c-e725031d3d28'	System	03 Sep 2020 16:40:46
User entered 'None (1)'	System	03 Sep 2020 16:40:46

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:43', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '09d1c172-0427-4175-923c-e725031d3d28'	System	03 Sep 2020 16:40:46
User entered '03 Sep 2020 11:40'	System	03 Sep 2020 16:40:46

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 11:14'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 13:44'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:27', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '063a5307-2488-4cc7-8ffb-4e065d1a1e49'	System	03 Sep 2020 23:58:39
User entered 'None (1)'	System	03 Sep 2020 23:58:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:30', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '063a5307-2488-4cc7-8ffb-4e065d1a1e49'	System	03 Sep 2020 23:58:39
User entered 'No (N)'	System	03 Sep 2020 23:58:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '063a5307-2488-4cc7-8ffb-4e065d1a1e49'	System	03 Sep 2020 23:58:39
User entered 'No (N)'	System	03 Sep 2020 23:58:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:35', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '063a5307-2488-4cc7-8ffb-4e065d1a1e49'	System	03 Sep 2020 23:58:39
User entered 'None (1)'	System	03 Sep 2020 23:58:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:37', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '063a5307-2488-4cc7-8ffb-4e065d1a1e49'	System	03 Sep 2020 23:58:39
User entered '03 Sep 2020 18:58'	System	03 Sep 2020 23:58:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 2'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '66b06e67-c059-4a3e-8156-d90e979ac3d5'	System	04 Sep 2020 23:44:22
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 23:44:22

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '66b06e67-c059-4a3e-8156-d90e979ac3d5'	System	04 Sep 2020 23:44:22
User entered 'No (N)'	System	04 Sep 2020 23:44:22

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:14', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '66b06e67-c059-4a3e-8156-d90e979ac3d5'	System	04 Sep 2020 23:44:22
User entered 'No (N)'	System	04 Sep 2020 23:44:22

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:16', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '66b06e67-c059-4a3e-8156-d90e979ac3d5'	System	04 Sep 2020 23:44:22
User entered 'None (1)'	System	04 Sep 2020 23:44:22

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:17', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '66b06e67-c059-4a3e-8156-d90e979ac3d5' User entered '04 Sep 2020 18:44'	System	04 Sep 2020 23:44:22
	System	04 Sep 2020 23:44:22

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 3'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:20', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f65267f-6017-491d-ac72-4ff7283294c3'	System	05 Sep 2020 23:33:49
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:33:49

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:29', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f65267f-6017-491d-ac72-4ff7283294c3'	System	05 Sep 2020 23:33:49
User entered 'No (N)'	System	05 Sep 2020 23:33:49

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f65267f-6017-491d-ac72-4ff7283294c3'	System	05 Sep 2020 23:33:49
User entered 'No (N)'	System	05 Sep 2020 23:33:49

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:35', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f65267f-6017-491d-ac72-4ff7283294c3'	System	05 Sep 2020 23:33:49
User entered 'None (1)'	System	05 Sep 2020 23:33:49

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:44', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f65267f-6017-491d-ac72-4ff7283294c3'	System	05 Sep 2020 23:33:49
User entered '05 Sep 2020 18:33'	System	05 Sep 2020 23:33:49

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 4'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:46', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e8c5fa3d-e04c-4f76-9423-1700c6f1bb0b'	System	06 Sep 2020 23:16:08
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:16:08

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e8c5fa3d-e04c-4f76-9423-1700c6f1bb0b'	System	06 Sep 2020 23:16:08
User entered 'No (N)'	System	06 Sep 2020 23:16:08

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:54', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e8c5fa3d-e04c-4f76-9423-1700c6f1bb0b'	System	06 Sep 2020 23:16:08
User entered 'No (N)'	System	06 Sep 2020 23:16:08

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:15:57', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e8c5fa3d-e04c-4f76-9423-1700c6f1bb0b'	System	06 Sep 2020 23:16:08
User entered 'None (1)'	System	06 Sep 2020 23:16:08

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'e8c5fa3d-e04c-4f76-9423-1700c6f1bb0b'	System	06 Sep 2020 23:16:08
User entered '06 Sep 2020 18:16'	System	06 Sep 2020 23:16:08

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 5'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:47', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7682ae6-000b-4039-b2c5-75b0e1dbec18'	System	07 Sep 2020 23:55:01
User entered 'None (1)'	System	07 Sep 2020 23:55:01

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:50', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7682ae6-000b-4039-b2c5-75b0e1dbec18'	System	07 Sep 2020 23:55:01
User entered 'No (N)'	System	07 Sep 2020 23:55:01

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:52', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7682ae6-000b-4039-b2c5-75b0e1dbec18'	System	07 Sep 2020 23:55:01
User entered 'No (N)'	System	07 Sep 2020 23:55:01

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7682ae6-000b-4039-b2c5-75b0e1dbec18'	System	07 Sep 2020 23:55:01
User entered 'None (1)'	System	07 Sep 2020 23:55:01

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:54:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7682ae6-000b-4039-b2c5-75b0e1dbec18'	System	07 Sep 2020 23:55:01
User entered '07 Sep 2020 18:54'	System	07 Sep 2020 23:55:01

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 6'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '86acdcbb-c0d5-45a7-afa1-a954e0eb410d'	System	08 Sep 2020 23:09:35
User entered 'None (1)'	System	08 Sep 2020 23:09:35

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:24', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '86acdcbb-c0d5-45a7-afa1-a954e0eb410d'	System	08 Sep 2020 23:09:35
User entered 'No (N)'	System	08 Sep 2020 23:09:35

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:25', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '86acdcbb-c0d5-45a7-afa1-a954e0eb410d'	System	08 Sep 2020 23:09:35
User entered 'No (N)'	System	08 Sep 2020 23:09:35

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:27', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '86acdcbb-c0d5-45a7-afa1-a954e0eb410d'	System	08 Sep 2020 23:09:35
User entered 'None (1)'	System	08 Sep 2020 23:09:35

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:30', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '86acdcbb-c0d5-45a7-afa1-a954e0eb410d'	System	08 Sep 2020 23:09:35
User entered '08 Sep 2020 18:09'	System	08 Sep 2020 23:09:35

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 7'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:49:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '804c6034-e15b-4af2-b9f3-43eb8dd99fd9'	System	09 Sep 2020 22:50:09
User entered 'None (1)'	System	09 Sep 2020 22:50:09

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:49:58', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '804c6034-e15b-4af2-b9f3-43eb8dd99fd9'	System	09 Sep 2020 22:50:09
User entered 'No (N)'	System	09 Sep 2020 22:50:09

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:01', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '804c6034-e15b-4af2-b9f3-43eb8dd99fd9'	System	09 Sep 2020 22:50:09
User entered 'No (N)'	System	09 Sep 2020 22:50:09

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:02', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '804c6034-e15b-4af2-b9f3-43eb8dd99fd9'	System	09 Sep 2020 22:50:09
User entered 'None (1)'	System	09 Sep 2020 22:50:09

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '804c6034-e15b-4af2-b9f3-43eb8dd99fd9'	System	09 Sep 2020 22:50:09
User entered '09 Sep 2020 17:50'	System	09 Sep 2020 22:50:09

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:47', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'None (0)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'None (0)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:51', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'None (0)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'None (0)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:55', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'None (0)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:40:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'None (0)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:41:01', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered 'No (N)'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T11:41:03', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd16c9d4e-9b70-4d05-ba28-350aaeb5bdce'	System	03 Sep 2020 16:41:05
User entered '03 Sep 2020 11:41'	System	03 Sep 2020 16:41:05

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 11:14'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 13:44'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:41', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'None (0)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'None (0)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:44', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'None (0)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:45', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'None (0)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:47', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'None (0)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'None (0)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:51', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered 'No (N)'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-03T18:58:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '7e59dcd1-29d4-4414-9f27-414e03e342c6'	System	03 Sep 2020 23:58:55
User entered '03 Sep 2020 18:58'	System	03 Sep 2020 23:58:55

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 2'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'None (0)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:22', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'None (0)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:24', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'None (0)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:26', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'None (0)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:28', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'None (0)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:29', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'None (0)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:32', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered 'No (N)'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-04T18:44:34', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '1877e026-9506-450d-a0cd-dfa2823e9e83'	System	04 Sep 2020 23:44:38
User entered '04 Sep 2020 18:44'	System	04 Sep 2020 23:44:38

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 3'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:54', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'None (0)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:53', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'None (0)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'None (0)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:57', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'None (0)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:58', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'None (0)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:33:59', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'None (0)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:34:02', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered 'No (N)'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-05T18:34:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '59013f31-1e60-4049-8711-e6dd381f1002'	System	05 Sep 2020 23:34:10
User entered '05 Sep 2020 18:34'	System	05 Sep 2020 23:34:10

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 4'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f' User entered 'None (0)'	System	06 Sep 2020 23:16:26
	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f' User entered 'None (0)'	System	06 Sep 2020 23:16:26
	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f' User entered 'None (0)'	System	06 Sep 2020 23:16:26
	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f' User entered 'None (0)'	System	06 Sep 2020 23:16:26
	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:16', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f' User entered 'None (0)'	System	06 Sep 2020 23:16:26
	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f' User entered 'None (0)'	System	06 Sep 2020 23:16:26
	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f'	System	06 Sep 2020 23:16:26
User entered 'No (N)'	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-06T18:16:23', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9646739e-528b-4d84-9f52-e485e710873f'	System	06 Sep 2020 23:16:26
User entered '06 Sep 2020 18:16'	System	06 Sep 2020 23:16:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 5'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:06', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'None (0)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'None (0)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:10', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'None (0)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'None (0)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'None (0)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:14', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'None (0)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered 'No (N)'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-07T18:55:17', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '02e5bbf0-e1c9-4465-8455-a70c63730c47'	System	07 Sep 2020 23:55:21
User entered '07 Sep 2020 18:55'	System	07 Sep 2020 23:55:21

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 6'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:33', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'None (0)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:34', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'None (0)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'None (0)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:38', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'None (0)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:39', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'None (0)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:40', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'None (0)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:44', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered 'No (N)'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-08T18:09:45', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '08fd04c1-8e60-4abb-af5f-4dcec384f160'	System	08 Sep 2020 23:09:48
User entered '08 Sep 2020 18:09'	System	08 Sep 2020 23:09:48

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	03 Sep 2020 16:01:39
User entered 'Day 7'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:10', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'None (0)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'None (0)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:12', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'None (0)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'None (0)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'None (0)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:17', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'None (0)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered 'No (N)'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cd442f955f9ba7c7)', Time: '2020-09-09T17:50:21', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5cfa114c-b554-4660-b7e3-f4847ed8f5db'	System	09 Sep 2020 22:50:26
User entered '09 Sep 2020 17:50'	System	09 Sep 2020 22:50:26

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:01:39

US3272060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:01:39

US3272060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:33:00

US3272060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 16:33:00

US3272060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 16:33:00

US3272060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:33:00

US3272060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:33:04

US3272060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:06
User entered 'I'	System	10 Sep 2020 16:33:04

US3272060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:28:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:55:21

US3272060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:28:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:55:21

US3272060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:28:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 15:55:21

US3272060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:28:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:55:21

US3272060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:28:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:55:24

US3272060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:28:36
User entered 'I'	System	17 Sep 2020 15:55:24

US3272060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:04:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:25:19

US3272060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:04:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '24 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:25:19

US3272060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:04:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 20:25:19

US3272060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:04:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:25:19

US3272060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:04:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:25:23

US3272060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:04:17
User entered 'I'	System	02 Oct 2020 20:25:23

US3272060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:14:29

US3272060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '01 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:14:29

US3272060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Oct 2020 18:14:29

US3272060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered 'VISIT3'	System	05 Oct 2020 18:14:29

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '01 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '14:19'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered '01 Oct 2020 14:19'	System	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '37.3' C	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '81'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered 'bpm'	System	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '16'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered 'breaths/min'	System	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '117'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered 'mmHg'	System	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '81'	(b) (4), (b) (6)	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered 'mmHg'	System	05 Oct 2020 18:15:13

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04

US3272060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04

US3272060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:15:23

US3272060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '01 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:15:23

US3272060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:16:04

US3272060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '01 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:16:04

US3272060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '14:16'	(b) (4), (b) (6)	05 Oct 2020 18:16:04

US3272060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered '01 Oct 2020 14:16'	System	05 Oct 2020 18:16:04

US3272060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:16:07

US3272060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:14:04
User entered '1'	System	05 Oct 2020 18:16:07

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 64'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-06T14:25:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'cca4f367-2758-4f21-a47c-d34323a52af0'	System	06 Oct 2020 19:25:17
User entered 'No (N)'	System	06 Oct 2020 19:25:17

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-06T14:25:10', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'cca4f367-2758-4f21-a47c-d34323a52af0'	System	06 Oct 2020 19:25:17
User entered 'No (N)'	System	06 Oct 2020 19:25:17

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-06T14:25:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'cca4f367-2758-4f21-a47c-d34323a52af0' User entered '06 Oct 2020 14:25:13'	System	06 Oct 2020 19:25:17
	System	06 Oct 2020 19:25:17

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 71'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-17T13:31:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c72b6857-530e-4da1-872a-7f1bc0ad1a42'	System	17 Oct 2020 18:31:21
User entered 'No (N)'	System	17 Oct 2020 18:31:21

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-17T13:31:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c72b6857-530e-4da1-872a-7f1bc0ad1a42'	System	17 Oct 2020 18:31:21
User entered 'No (N)'	System	17 Oct 2020 18:31:21

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-17T13:31:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c72b6857-530e-4da1-872a-7f1bc0ad1a42'	System	17 Oct 2020 18:31:21
User entered '17 Oct 2020 13:31:18'	System	17 Oct 2020 18:31:21

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 78'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-20T09:21:22', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'db60f1b7-02a7-4e52-9997-0304c4d5b484'	System	16 Oct 2020 14:21:29
User entered 'No (N)'	System	16 Oct 2020 14:21:29

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-20T09:21:25', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'db60f1b7-02a7-4e52-9997-0304c4d5b484'	System	16 Oct 2020 14:21:29
User entered 'No (N)'	System	16 Oct 2020 14:21:29

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-10-20T09:21:27', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'db60f1b7-02a7-4e52-9997-0304c4d5b484'	System	16 Oct 2020 14:21:29
User entered '20 Oct 2020 09:21:27'	System	16 Oct 2020 14:21:29

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 92'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-04T06:49:11', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '46722fd1-4514-47d8-8c6c-fd325f625ebb'	System	04 Nov 2020 12:49:20
User entered 'No (N)'	System	04 Nov 2020 12:49:20

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-04T06:49:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '46722fd1-4514-47d8-8c6c-fd325f625ebb'	System	04 Nov 2020 12:49:20
User entered 'No (N)'	System	04 Nov 2020 12:49:20

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-04T06:49:20', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '46722fd1-4514-47d8-8c6c-fd325f625ebb'	System	04 Nov 2020 12:49:20
User entered '04 Nov 2020 06:49:20'	System	04 Nov 2020 12:49:20

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 99'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-10T07:45:36', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd2de024e-5077-45a9-a130-af65d141d077'	System	10 Nov 2020 13:45:48
User entered 'No (N)'	System	10 Nov 2020 13:45:48

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-10T07:45:42', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd2de024e-5077-45a9-a130-af65d141d077'	System	10 Nov 2020 13:45:48
User entered 'No (N)'	System	10 Nov 2020 13:45:48

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-10T07:45:44', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd2de024e-5077-45a9-a130-af65d141d077'	System	10 Nov 2020 13:45:48
User entered '10 Nov 2020 07:45:44'	System	10 Nov 2020 13:45:48

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered 'Day 106'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-17T19:35:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd64f154e-2147-4558-9314-448b35b2e410'	System	18 Nov 2020 01:35:27
User entered 'No (N)'	System	18 Nov 2020 01:35:27

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-17T19:35:22', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd64f154e-2147-4558-9314-448b35b2e410'	System	18 Nov 2020 01:35:27
User entered 'No (N)'	System	18 Nov 2020 01:35:27

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-17T19:35:24', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd64f154e-2147-4558-9314-448b35b2e410' User entered '17 Nov 2020 19:35:24'	System	18 Nov 2020 01:35:27
	System	18 Nov 2020 01:35:27

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 17:37:49

US3272060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:35:40
Data entry locked.	System	06 Aug 2020 17:37:49
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 17:37:49

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2020-11-21T06:33:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '568c56a5-23f6-4c04-8337-d0d83c02c3c6'	System	21 Nov 2020 12:33:10
User entered 'No (N)'	System	21 Nov 2020 12:33:10

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2020-11-21T06:33:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '568c56a5-23f6-4c04-8337-d0d83c02c3c6'	System	21 Nov 2020 12:33:10
User entered 'No (N)'	System	21 Nov 2020 12:33:10

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-11-21T06:33:08', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '568c56a5-23f6-4c04-8337-d0d83c02c3c6'	System	21 Nov 2020 12:33:10
User entered '21 Nov 2020 06:33:08'	System	21 Nov 2020 12:33:10

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2020-12-01T15:29:18', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '454418fb-2c9c-4f47-9629-ddad496bebc8'	System	01 Dec 2020 21:29:24
User entered 'No (N)'	System	01 Dec 2020 21:29:24

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2020-12-01T15:29:20', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '454418fb-2c9c-4f47-9629-ddad496bebc8'	System	01 Dec 2020 21:29:24
User entered 'No (N)'	System	01 Dec 2020 21:29:24

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-12-01T15:29:22', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '454418fb-2c9c-4f47-9629-ddad496bebc8'	System	01 Dec 2020 21:29:24
User entered '01 Dec 2020 15:29:22'	System	01 Dec 2020 21:29:24

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2020-12-23T16:33:43', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ea894ad8-3b4b-4e44-a39f-f07436399c8f'	System	23 Dec 2020 22:33:54
User entered 'No (N)'	System	23 Dec 2020 22:33:54

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2020-12-23T16:33:45', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ea894ad8-3b4b-4e44-a39f-f07436399c8f'	System	23 Dec 2020 22:33:54
User entered 'No (N)'	System	23 Dec 2020 22:33:54

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-12-23T16:33:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'ea894ad8-3b4b-4e44-a39f-f07436399c8f' User entered '23 Dec 2020 16:33:49'	System	23 Dec 2020 22:33:54
	System	23 Dec 2020 22:33:54

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2020-12-27T14:17:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '869f8736-0206-4880-869f-d296b297bbd6'	System	27 Dec 2020 20:17:19
User entered 'No (N)'	System	27 Dec 2020 20:17:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2020-12-27T14:17:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '869f8736-0206-4880-869f-d296b297bbd6'	System	27 Dec 2020 20:17:19
User entered 'No (N)'	System	27 Dec 2020 20:17:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2020-12-27T14:17:15', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '869f8736-0206-4880-869f-d296b297bbd6'	System	27 Dec 2020 20:17:19
User entered '27 Dec 2020 14:17:15'	System	27 Dec 2020 20:17:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-01-03T14:22:25', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4f075194-8563-4ccf-85ea-b08801af6693'	System	03 Jan 2021 20:22:36
User entered 'No (N)'	System	03 Jan 2021 20:22:36

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-01-03T14:22:28', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4f075194-8563-4ccf-85ea-b08801af6693'	System	03 Jan 2021 20:22:36
User entered 'No (N)'	System	03 Jan 2021 20:22:36

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-01-03T14:22:32', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '4f075194-8563-4ccf-85ea-b08801af6693'	System	03 Jan 2021 20:22:36
User entered '03 Jan 2021 14:22:32'	System	03 Jan 2021 20:22:36

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-01-10T15:34:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c4cd2df5-acc6-43db-9608-81486e5505b3'	System	10 Jan 2021 21:34:13
User entered 'No (N)'	System	10 Jan 2021 21:34:13

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-01-10T15:34:09', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c4cd2df5-acc6-43db-9608-81486e5505b3'	System	10 Jan 2021 21:34:13
User entered 'No (N)'	System	10 Jan 2021 21:34:13

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-01-10T15:34:12', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'c4cd2df5-acc6-43db-9608-81486e5505b3'	System	10 Jan 2021 21:34:13
User entered '10 Jan 2021 15:34:12'	System	10 Jan 2021 21:34:13

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-01-16T03:02:31', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b3640253-b056-456a-a156-08c3b81caa27'	System	16 Jan 2021 09:02:44
User entered 'No (N)'	System	16 Jan 2021 09:02:44

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-01-16T03:02:38', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b3640253-b056-456a-a156-08c3b81caa27'	System	16 Jan 2021 09:02:44
User entered 'No (N)'	System	16 Jan 2021 09:02:44

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-01-16T03:02:41', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'b3640253-b056-456a-a156-08c3b81caa27'	System	16 Jan 2021 09:02:44
User entered '16 Jan 2021 03:02:41'	System	16 Jan 2021 09:02:44

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-01-23T12:00:04', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8e367410-9e5f-4459-953a-124dd555a86f'	System	23 Jan 2021 18:00:19
User entered 'No (N)'	System	23 Jan 2021 18:00:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-01-23T12:00:10', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8e367410-9e5f-4459-953a-124dd555a86f'	System	23 Jan 2021 18:00:19
User entered 'No (N)'	System	23 Jan 2021 18:00:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-01-23T12:00:13', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8e367410-9e5f-4459-953a-124dd555a86f'	System	23 Jan 2021 18:00:19
User entered '23 Jan 2021 12:00:13'	System	23 Jan 2021 18:00:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-02-01T12:00:43', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f3fff82-6462-43c4-934f-dc2918e369de'	System	01 Feb 2021 18:02:02
User entered 'No (N)'	System	01 Feb 2021 18:02:02

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-02-01T12:00:48', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f3fff82-6462-43c4-934f-dc2918e369de'	System	01 Feb 2021 18:02:02
User entered 'No (N)'	System	01 Feb 2021 18:02:02

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-01T12:00:50', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8f3fff82-6462-43c4-934f-dc2918e369de'	System	01 Feb 2021 18:02:02
User entered '01 Feb 2021 12:00:50'	System	01 Feb 2021 18:02:02

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-02-06T11:56:56', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7401514-0dd9-4360-afb7-28e5661452a0'	System	06 Feb 2021 17:57:05
User entered 'No (N)'	System	06 Feb 2021 17:57:05

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-02-06T11:57:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7401514-0dd9-4360-afb7-28e5661452a0'	System	06 Feb 2021 17:57:05
User entered 'No (N)'	System	06 Feb 2021 17:57:05

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-06T11:57:03', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'd7401514-0dd9-4360-afb7-28e5661452a0'	System	06 Feb 2021 17:57:05
User entered '06 Feb 2021 11:57:03'	System	06 Feb 2021 17:57:05

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-02-13T07:28:49', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5498f69b-98e8-4b2b-b7a4-fdd9d53dc4f0'	System	13 Feb 2021 13:29:01
User entered 'No (N)'	System	13 Feb 2021 13:29:01

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-02-13T07:28:54', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5498f69b-98e8-4b2b-b7a4-fdd9d53dc4f0'	System	13 Feb 2021 13:29:01
User entered 'No (N)'	System	13 Feb 2021 13:29:01

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-13T07:28:58', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '5498f69b-98e8-4b2b-b7a4-fdd9d53dc4f0'	System	13 Feb 2021 13:29:01
User entered '13 Feb 2021 07:28:58'	System	13 Feb 2021 13:29:01

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-02-20T15:38:14', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95a7e122-2c28-4784-a016-d247eef34771'	System	20 Feb 2021 21:38:22
User entered 'No (N)'	System	20 Feb 2021 21:38:22

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-02-20T15:38:17', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95a7e122-2c28-4784-a016-d247eef34771'	System	20 Feb 2021 21:38:22
User entered 'No (N)'	System	20 Feb 2021 21:38:22

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-20T15:38:19', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '95a7e122-2c28-4784-a016-d247eef34771'	System	20 Feb 2021 21:38:22
User entered '20 Feb 2021 15:38:19'	System	20 Feb 2021 21:38:22

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-02-27T09:22:47-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '985db868-0a5e-40d3-b596-d35ec40a4c17'	System	27 Feb 2021 15:22:56
User entered 'No (N)'	System	27 Feb 2021 15:22:56

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-02-27T09:22:51-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '985db868-0a5e-40d3-b596-d35ec40a4c17'	System	27 Feb 2021 15:22:56
User entered 'No (N)'	System	27 Feb 2021 15:22:56

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-27T09:22:53-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '985db868-0a5e-40d3-b596-d35ec40a4c17' User entered '27 Feb 2021 09:22:53'	System	27 Feb 2021 15:22:56
	System	27 Feb 2021 15:22:56

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-03-06T01:15:10-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9a15f1e1-0eb5-4868-98e2-5c65ef0246eb' User entered 'No (N)'	System	06 Mar 2021 07:15:26
	System	06 Mar 2021 07:15:26

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-03-06T01:15:20-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9a15f1e1-0eb5-4868-98e2-5c65ef0246eb'	System	06 Mar 2021 07:15:26
User entered 'No (N)'	System	06 Mar 2021 07:15:26

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-03-06T01:15:22-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '9a15f1e1-0eb5-4868-98e2-5c65ef0246eb' User entered '06 Mar 2021 01:15:22'	System	06 Mar 2021 07:15:26
	System	06 Mar 2021 07:15:26

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-03-15T12:30:24-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '61d8fd35-6a02-42ac-81ea-82f011f857a8'	System	15 Mar 2021 17:30:51
User entered 'No (N)'	System	15 Mar 2021 17:30:51

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-03-15T12:30:27-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '61d8fd35-6a02-42ac-81ea-82f011f857a8'	System	15 Mar 2021 17:30:51
User entered 'No (N)'	System	15 Mar 2021 17:30:51

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-03-15T12:30:29-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '61d8fd35-6a02-42ac-81ea-82f011f857a8' User entered '15 Mar 2021 12:30:29'	System	15 Mar 2021 17:30:51
	System	15 Mar 2021 17:30:51

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-03-21T08:58:47-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8c88f6b7-1385-459f-9ac9-67b843bba801'	System	21 Mar 2021 13:58:58
User entered 'No (N)'	System	21 Mar 2021 13:58:58

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-03-21T08:58:50-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8c88f6b7-1385-459f-9ac9-67b843bba801'	System	21 Mar 2021 13:58:58
User entered 'No (N)'	System	21 Mar 2021 13:58:58

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-03-21T08:58:56-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8c88f6b7-1385-459f-9ac9-67b843bba801'	System	21 Mar 2021 13:58:58
User entered '21 Mar 2021 08:58:56'	System	21 Mar 2021 13:58:58

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-03-29T08:31:12-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8be106d7-2ba3-423d-9509-2d765719fb65'	System	29 Mar 2021 13:31:23
User entered 'No (N)'	System	29 Mar 2021 13:31:23

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-03-29T08:31:16-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8be106d7-2ba3-423d-9509-2d765719fb65'	System	29 Mar 2021 13:31:23
User entered 'No (N)'	System	29 Mar 2021 13:31:23

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-03-29T08:31:19-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '8be106d7-2ba3-423d-9509-2d765719fb65'	System	29 Mar 2021 13:31:23
User entered '29 Mar 2021 08:31:19'	System	29 Mar 2021 13:31:23

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-04-26T12:53:33-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88ed7376-bb09-4746-854f-92d8b31e02a4'	System	26 Apr 2021 17:53:43
User entered 'No (N)'	System	26 Apr 2021 17:53:43

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-04-26T12:53:37-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88ed7376-bb09-4746-854f-92d8b31e02a4'	System	26 Apr 2021 17:53:43
User entered 'No (N)'	System	26 Apr 2021 17:53:43

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-04-26T12:53:39-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: '88ed7376-bb09-4746-854f-92d8b31e02a4'	System	26 Apr 2021 17:53:43
User entered '26 Apr 2021 12:53:39'	System	26 Apr 2021 17:53:43

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[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 (20672044d260b03a)', Time: '2021-05-02T09:13:32-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f406ae13-3f93-4a41-b97a-ba582357af6d'	System	02 May 2021 14:13:40
User entered 'No (N)'	System	02 May 2021 14:13:40

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

Have you been exposed to someone with 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 (20672044d260b03a)', Time: '2021-05-02T09:13:35-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f406ae13-3f93-4a41-b97a-ba582357af6d'	System	02 May 2021 14:13:40
User entered 'No (N)'	System	02 May 2021 14:13:40

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-05-02T09:13:38-05:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f406ae13-3f93-4a41-b97a-ba582357af6d'	System	02 May 2021 14:13:40
User entered '02 May 2021 09:13:38'	System	02 May 2021 14:13:40

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:43:19

US3272060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:19
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:43:19

US3272060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:23:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:27:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-27T09:23:05-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f4329199-23dc-401b-a39a-1ab4b869125e'	System	27 Feb 2021 15:23:10
User entered 'No (N)'	System	27 Feb 2021 15:23:10

US3272060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:23:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:27:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20672044d260b03a)', Time: '2021-02-27T09:23:07-06:00', User OID: 'PatientReportedOutcome (US3272060)', ODM File OID: 'f4329199-23dc-401b-a39a-1ab4b869125e' User entered '27 Feb 2021 09:23:07'	System	27 Feb 2021 15:23:10
	System	27 Feb 2021 15:23:10

US3272060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 19:48:26

US3272060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 19:48:26

US3272060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Oct 2020 19:48:26

US3272060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 19:48:26

US3272060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 19:48:36

US3272060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:55
User entered 'I'	System	26 Oct 2020 19:48:36

US3272060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Kayla Flege (b) (4)	30 Nov 2020 17:53:28

US3272060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '30 Nov 2020'	Kayla Flege (b) (4)	30 Nov 2020 17:53:28

US3272060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4)	30 Nov 2020 17:53:28

US3272060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Kayla Flege (b) (4)	30 Nov 2020 17:53:28

US3272060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Kayla Flege (b) (4)	30 Nov 2020 17:53:34

US3272060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:46
User entered 'I'	System	30 Nov 2020 17:53:34

US3272060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:14:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 19:55:07

US3272060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:14:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '30 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 19:55:07

US3272060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:14:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Jan 2021 19:55:07

US3272060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:14:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:55:07

US3272060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:14:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 19:55:14

US3272060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:14:44
User entered 'I'	System	28 Jan 2021 19:55:14

US3272060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:27:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 19:55:32

US3272060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:27:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 19:55:32

US3272060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:27:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Jan 2021 19:55:32

US3272060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:27:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:55:32

US3272060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:27:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 19:55:38

US3272060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:27:06
User entered 'I'	System	28 Jan 2021 19:55:38

US3272060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 20:12:19

US3272060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '26 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 20:12:19

US3272060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Clinic (Clinic)'	Andrea Clement (b) (4)	01 Mar 2021 20:12:19

US3272060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered 'VISIT4'	System	01 Mar 2021 20:12:19

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	30 Mar 2021 23:44:40

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48

US3272060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48

US3272060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 20:12:38

US3272060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '26 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 20:12:38

US3272060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 20:13:50

US3272060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '26 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 20:13:50

US3272060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '13:27'	Andrea Clement (b) (4)	01 Mar 2021 20:13:50

US3272060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered '26 Feb 2021 13:27'	System	01 Mar 2021 20:13:50

US3272060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 20:13:59

US3272060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered 'I'	System	01 Mar 2021 20:13:59

US3272060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 17:59:12

US3272060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '29 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 17:59:12

US3272060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Apr 2021 17:59:12

US3272060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 17:59:12

US3272060

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 17:59:19

US3272060

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 17:59:19

US3272060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 15:19:04

US3272060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '28 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 15:19:04

US3272060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Apr 2021 15:19:04

US3272060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 15:19:04

US3272060

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 15:19:10

US3272060

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 15:19:10

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 21:20:58

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 21:20:58

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Jan 2021 21:20:58

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 21:20:58

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 13:19:27
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:43:16

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 15:56:59
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:20:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 13:19:27
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		22 Apr 2021 06:36:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:43:16

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User entered empty.	System	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:23:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User entered empty.	System	20 Jan 2021 21:21:32

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 21:21:42

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 21:21:42

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10:11'	(b) (4), (b) (6)	20 Jan 2021 21:21:42

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User entered '15 Jan 2021 10:11'	System	20 Jan 2021 21:21:42

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 21:21:55

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 21:21:55

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:20

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '10:13'	(b) (4), (b) (6)	20 Jan 2021 21:21:55

US3272060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:20

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:01:06
User entered '15 Jan 2021 10:13'	System	20 Jan 2021 21:21:55

US3272060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:23:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:06:21
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	26 Feb 2021 19:49:02
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:22:49

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:53:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:53:54
Data point term sent to Coder	System	26 Feb 2021 19:53:33
User entered 'Worsening of depression'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '21 Feb 2021'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '1'	Whitney West (b) (4) (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 19:53:16

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'USA-US070-2021-mRNA-1273-P301000007'	System	01 Mar 2021 18:27:08
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 18:27:08

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 20:12:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 20:12:53
Data point term sent to Coder	System	26 Feb 2021 20:12:11
User entered 'Suicide attempt'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '21 Feb 2021'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '21 Feb 2021'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Feb 2021 20:27:16
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '1'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 00:53:07
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:05:20
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 00:53:15
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 00:53:07
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:08:32
User entered '1'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'PV Query: Please provide doctor's notes/labs with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 13:35:31
Query 'PV Query: Please provide doctor's notes/labs with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Copy was sent today. ' (Site from Safety).	Whitney West (b) (4)	29 Mar 2021 21:37:03
User closed query 'Per DM CLR: Narrative indicates that the subject was initiated with Lithium 150 mg PO daily. However, there is no recorded ConMed that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:25:49

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'COMPLAINS OF RECENT WORSENING OF DEPRESSION CULMINATING IN A SUICIDE ATTEMPT 21FEB2021. SUBJECT HAS HISTORY OF MODERATE DEPRESSION AND ADHD AND WAS STABLE ON HIS MEDICAL REGIMEN. HAD RECENT LOSS OF EMPLOYMENT THAT UPSET HIS ROUTINE AND WORSENE SYMPTOMS. SUBJECT (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) WAS NOT HOSPITALIZED OR TAKEN INTO CUSTODY, HIS MOTHER TOOK HIM TO HIS DOCTOR FOR EVALUATION WHERE HE INITIATED LITHIUM 150 MG PO DAILY. IS CURRENTLY STABLE WITH NO SUICIDAL OR SELF-HARM IDEATION, HAS WEEKLY APPOINTMENTS WITH PROVIDER. Medical record relates incident as self-harm attempt, not a suicide attempt. Diagnoses of Asperger's syndrome and moderate, recurrent, major depressive disorder. Following up with therapist weekly and with psychiatry monthly.' reason for change: New Information	Whitney West (b) (4) (b) (4)	24 Mar 2021 21:24:41
Query 'Per DM CLR: Narrative indicates that the subject was initiated with Lithium 150 mg PO daily. However, there is no recorded ConMed that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'Lithium added. Thank you! ' (Site from DM).	Whitney West (b) (4) (b) (4)	24 Mar 2021 21:05:36
User opened query 'Per DM CLR: Narrative indicates that the subject was initiated with Lithium 150 mg PO daily. However, there is no recorded ConMed that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:28:42

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide doctor's notes/labs with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:37:34
User entered 'Complains of recent worsening of depression culminating in a suicide attempt 21FEB2021. Subject has history of moderate depression and ADHD and was stable on his medical regimen. Had recent loss of employment that upset his routine and worsened symptoms. Subject (b) (6)	Whitney West (b) (4)	26 Feb 2021 20:11:50
Was not hospitalized or taken into custody, his mother took him to his doctor for evaluation where he initiated Lithium 150 mg PO daily. Is currently stable with no suicidal or self-harm ideation, has weekly appointments with provider. Sending request for medical records. Participant agrees with plan.'		

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 20:11:50

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm why this was assessed as AE and not entered in MH CRF. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 06:37:16
Query 'Per MM: please confirm why this was assessed as AE and not entered in MH CRF. ' answered with 'this is a new diagnosis. Subject was diagnosed with this after screening visit 23Fed2021' (Site from DM).		30 Apr 2021 18:46:19
User opened query 'Per MM: please confirm why this was assessed as AE and not entered in MH CRF. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:16:09
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as SOC: Psychiatric disorders, HLT: Developmental disorders NEC, HLT: Pervasive developmental disorders NEC, PT: Autism spectrum disorder, LLT: Asperger's syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:59:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:59:41
Data point term sent to Coder	System	24 Mar 2021 21:59:08
User entered 'Asperger's syndrome'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '23 Feb 2021'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:58:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 21:58:48
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 21:58:48
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:58:42
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'None (NONE)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '1' reason for change: Data Entry Error	Whitney West (b) (4)	07 Apr 2021 14:55:14
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:36:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Data entry error. ' (Site from DM).	Whitney West (b) (4)	07 Apr 2021 14:55:45
User entered '0' reason for change: Data Entry Error	Whitney West (b) (4)	07 Apr 2021 14:55:14
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 10:29:18
User entered '1'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 21:58:42

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 21:58:48

US3272060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 21:58:42

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:23:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:06:21
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:47:07

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:24:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:24:21
Data point term sent to Coder	System	07 Aug 2020 22:48:38
User entered 'Aripiprazole'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'attention deficit hyperactive disorder'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '10'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:01:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:48:15
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:48:15

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: ATOMOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: STRATTERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 22:52:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 22:52:19
Data point term sent to Coder	System	07 Aug 2020 22:50:44
User entered 'Strattera'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Attention Deficit Hyperactivity Disorder'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '80'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:01:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:50:10
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:50:10

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM CARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:01:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:01:41
Data point term sent to Coder	System	24 Mar 2021 19:07:09
User entered 'Lithium Carbonate'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Worsening depression'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '150'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '22 Feb 2021'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 19:06:12
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	23 Mar 2021 20:16:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	22 Sep 2020 00:03:45

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUVOXAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 00:04:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 00:04:18
Data point term sent to Coder	System	07 Aug 2020 22:52:46
User entered 'Fluxoxamine'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Depression'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '300'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:41:10
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify. answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:04:08
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 04:36:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:02:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:52:13
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:52:13

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 22:54:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 22:54:20
Data point term sent to Coder	System	07 Aug 2020 22:53:47
User entered 'Buspar'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Depression'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '10'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:41:46
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify. answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:04:24
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 04:36:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:02:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:52:56
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:52:56

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:16:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:16:17
Data point term sent to Coder	System	07 Aug 2020 22:54:48
User entered 'Clonidine'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Attention Deficit Hyperactivity Disorder'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0.2'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:03:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:53:58
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:53:58

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: CLOZAPINE, PRODUCTSYNONYM: CLOZARIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 22:56:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 22:56:22
Data point term sent to Coder	System	07 Aug 2020 22:55:49
User entered 'Clozaril'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Attention Deficit Hyperactivity Disorder'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '50'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:03:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:55:17
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:55:17

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:26:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:26:08
Data point term sent to Coder	System	07 Aug 2020 22:56:52
User entered 'Melatonin'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Attention Deficit Hyperactivity Disorder'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '3'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:03:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 22:56:24
User entered 'un UNK 2019'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 22:56:24

US3272060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:23:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:51:57
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:56:43

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'USA-US070-2021-MRNA-1273-P301000007'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Adam'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Brosz'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '2444 W. Faidley Ave'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Grand Island'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'NE'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '68803'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'US'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 13:28:17
User entered '2'	System	15 Mar 2021 15:07:25
User entered '1'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'USA-US070-2021-MRNA-1273-P301000007'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Adam'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Brosz'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '2444 W. Faidley Ave'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Grand Island'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'NE'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '68803'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'US'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 13:28:17
User entered '2'	System	15 Mar 2021 15:07:25
User entered '1'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:23:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '01/Mar/2021 13:27'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:23:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'I'		01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'USA-US070-2021-MRNA-1273-P301000007'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Adam'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Brosz'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '2444 W. Faidley Ave'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Grand Island'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'NE'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '68803'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'US'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 13:28:17
User entered '2'	System	15 Mar 2021 15:07:25
User entered '1'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:23:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '15/Mar/2021 11:07'	System	15 Mar 2021 15:07:25

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:23:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 15:07:30
User entered 'I'		15 Mar 2021 15:07:25

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'USA-US070-2021-MRNA-1273-P301000007'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Yes (Y)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'No (N)'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Adam'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Brosz'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '2444 W. Faidley Ave'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'Grand Island'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'NE'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered '68803'	System	01 Mar 2021 18:27:08

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:27:36
User entered 'US'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 13:28:17
User entered '2'	System	15 Mar 2021 15:07:25
User entered '1'	System	01 Mar 2021 18:27:22

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:23:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered '25/Mar/2021 13:28'	System	25 Mar 2021 13:28:17

US3272060

Folder: SAE USA-US070-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:23:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:07:21
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:28:17