

US3272116 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:13:55

All time stamps listed in this document are displayed in GMT

US3272116

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 17:28:43

Generated On: 11 Aug 2021 22:13:55

Participant ID

US3272116

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

US3272116

Folder: Screening

Form: Visit Date

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

Generated On: 11 Aug 2021 22:13:55

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

Visit date (dd MMM yyyy)	12 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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US3272116

Folder: Screening

Form: Demographics

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

Generated On: 11 Aug 2021 22:13:55

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3272116

Folder: Screening

Form: Enrollment

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

Generated On: 11 Aug 2021 22:13:55

Date of Informed Consent (*dd MMM yyyy*) 12 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

US3272116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

Generated On: 11 Aug 2021 22:13:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3272116

Folder: Screening

Form: Medical History Summary

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

Generated On: 11 Aug 2021 22:13:55

Were any significant conditions reported?

Yes ☒

No ☐

US3272116

Folder: Screening

Form: Medical History (1)

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

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: Screening

Form: Vital Signs

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

Generated On: 11 Aug 2021 22:13:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:40
Height (xxx.x)	162.0 cm
Weight (xxx.x)	66.0 kg
BMI (xxx.x)	25.14861 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)	

US3272116

Folder: Screening

Form: Physical Examination

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

Generated On: 11 Aug 2021 22:13:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3272116

Folder: Screening

Form: Childbearing Potential

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

Generated On: 11 Aug 2021 22:13:55

Date of assessment (dd MMM yyyy) 12 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3272116

Folder: Screening

Form: Pregnancy Test

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

Generated On: 11 Aug 2021 22:13:55

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 12 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3272116

Folder: Screening

Form: Risk of Exposure

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

Generated On: 11 Aug 2021 22:13:55

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3272116

Folder: Screening

Form: Risk of Exposure

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

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3272116

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:28:52

Generated On: 11 Aug 2021 22:13:55

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

Visit date (dd MMM yyyy)	12 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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US3272116

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 17:28:52

Generated On: 11 Aug 2021 22:13:55

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103506

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 ☒

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 17:28:53

Generated On: 11 Aug 2021 22:13:55

Height	ND - Not Done
Weight	ND - Not Done

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:28:53

Generated On: 11 Aug 2021 22:13:55

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)	12 AUG 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:40
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:28:53

Generated On: 11 Aug 2021 22:13:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	13:04 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:04
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 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)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3272116

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 17:28:52

Generated On: 11 Aug 2021 22:13:55

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 12:30

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

US3272116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 AUG 2020

Collection time (00:00-23:59)

11:45 (24 HR)

Collection date and time (derived)

12 AUG 2020 11:45

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:41	12 AUG 2020 11:41
Nasopharyngeal Swab 2	No		

US3272116

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

97.8 °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 13:00

PC Open Date & Time

12 AUG 2020 12:50

PC Close Date & Time

12 AUG 2020 15:20

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	12 AUG 2020 19:53
PC Open Date & Time	12 AUG 2020 16:15
PC Close Date & Time	13 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

98.0 °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

13 AUG 2020 17:43

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 00:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

98.1 °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

17 AUG 2020 09:54

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

18 AUG 2020 09:10

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

12 AUG 2020 13:01

PC Open Date & Time

12 AUG 2020 12:50

PC Close Date & Time

12 AUG 2020 15:20

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

12 AUG 2020 19:55

PC Open Date & Time

12 AUG 2020 16:15

PC Close Date & Time

13 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 17:49

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

14 AUG 2020 20:43

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

16 AUG 2020 00:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

17 AUG 2020 09:55

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

18 AUG 2020 09:10

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 13:01
PC Open Date & Time	12 AUG 2020 12:50
PC Close Date & Time	12 AUG 2020 15:20

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 19:55
PC Open Date & Time	12 AUG 2020 16:15
PC Close Date & Time	13 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 ☒

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:50
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

47 of 2240

EAB) (1725)

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:43
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

49 of 2240

EAB) (1725)

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 00:26
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 ☒

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 09:55
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

53 of 2240

EAB) (1725)

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 09:10
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

Yes ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 13:31
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3272116

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 8

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 19 AUG 2020 13:31

PC Open Date and Time 19 AUG 2020 12:00

PC Close Date and Time 20 AUG 2020 11:59

US3272116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:50

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:50

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:48

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:48

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:49

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:49

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

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)	14 SEP 2020
Time of assessment (00:00-23:59)	07:48 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 07:48
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:54
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	14 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:28:53

Generated On: 11 Aug 2021 22:13:55

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 08:22 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 08:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3272116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:28:54

Generated On: 11 Aug 2021 22:13:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 SEP 2020

Collection time (00:00-23:59)

09:18 (24 HR)

Collection date and time (derived)

09 SEP 2020 09:18

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:28:53

Generated On: 11 Aug 2021 22:13:55

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:06	09 SEP 2020 09:06
Nasopharyngeal Swab 2	No		

US3272116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:53

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

98.3 °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

14 SEP 2020 08:54

PC Open Date & Time

14 SEP 2020 08:42

PC Close Date & Time

14 SEP 2020 11:12

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 97.9 °F

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

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

PC Time Stamp	14 SEP 2020 20:13
PC Open Date & Time	14 SEP 2020 12:07
PC Close Date & Time	15 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

16 SEP 2020 05:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

17 SEP 2020 07:12

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 08:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 20 SEP 2020 06:19

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 21 SEP 2020 10:43

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

14 SEP 2020 08:55

PC Open Date & Time

14 SEP 2020 08:42

PC Close Date & Time

14 SEP 2020 11:12

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

29

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 20:16

PC Open Date & Time

14 SEP 2020 12:07

PC Close Date & Time

15 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

16 SEP 2020 05:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

17 SEP 2020 07:13

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

19 SEP 2020 08:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

20 SEP 2020 06:20

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

21 SEP 2020 10:43

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 08:55
PC Open Date & Time	14 SEP 2020 08:42
PC Close Date & Time	14 SEP 2020 11:12

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 20:16
PC Open Date & Time	14 SEP 2020 12:07
PC Close Date & Time	15 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 ☒

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 05:26
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 ☒

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 07:13
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 ☒

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 08:11
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 ☒

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 06:20
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

104 of 2240

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 10:43
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3272116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:49

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:49

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:50

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:50

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:50

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:50

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:05
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3272116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:14 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:14

US3272116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 06:27:32

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 10:03:29
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

09 NOV 2020 16:21:33

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

17 NOV 2020 16:47:14

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 11:44:23

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

27 NOV 2020 08:42:00

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 DEC 2020 00:04:58
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 22:16:44

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2020 00:01
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Patient Cloud Close Date & Time	29 DEC 2020 23:59
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US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

01 JAN 2021 17:22:18

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

10 JAN 2021 07:55:38

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

15 JAN 2021 11:08:00

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

22 JAN 2021 13:30:21

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

29 JAN 2021 09:04:05

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

05 FEB 2021 11:57:31

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

12 FEB 2021 18:49:18

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 FEB 2021 08:43:53
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

27 FEB 2021 13:46:48

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

07 MAR 2021 10:13:44

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

02 APR 2021 09:27:56

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 15:11:24

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 11:53:33

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 15:46:40

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

30 APR 2021 06:05:10

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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25 MAY 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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01 JUN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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08 JUN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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11 JUN 2021 00:01

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15 JUN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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22 JUN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

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29 JUN 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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06 JUL 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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13 JUL 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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27 JUL 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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08 FEB 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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22 FEB 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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25 FEB 2022 00:01

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01 MAR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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04 MAR 2022 00:01

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08 MAR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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15 MAR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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18 MAR 2022 00:01

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22 MAR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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25 MAR 2022 00:01

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29 MAR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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01 APR 2022 00:01

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05 APR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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12 APR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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15 APR 2022 00:01

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19 APR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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22 APR 2022 00:01

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26 APR 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

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29 APR 2022 00:01

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03 MAY 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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 ☐

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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"/>

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3272116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:13:55

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 13:46:57

US3272116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:51

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:48

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:48

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:48

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:48

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:28:49

Generated On: 11 Aug 2021 22:13:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272116

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:28:49

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

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

Visit date (dd MMM yyyy)	18 MAR 2021
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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	VISIT4
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US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

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) _____

US3272116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3272116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 18 MAR 2021

Collection time (00:00-23:59) 13:30 (24 HR)

Collection date and time (derived) 18 MAR 2021 13:30

US3272116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:29:10

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 17:28:44

Generated On: 11 Aug 2021 22:13:55

Date of Contact	19 FEB 2021
Time of Contact	10:20
Date and Time of Contact (derived)	19 FEB 2021 10:20
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

322 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

326 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 FEB 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

338 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2240

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 17:28:45

Generated On: 11 Aug 2021 22:13:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 17:28:43

Generated On: 11 Aug 2021 22:13:55

Date of Visit	19 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	19 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Apr 2021 17:28:44

Generated On: 11 Aug 2021 22:13:55

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 17:28:46

Generated On: 11 Aug 2021 22:13:55

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 FEB 2021
Day 5	Yes	23 FEB 2021
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3272116

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:28:46

Generated On: 11 Aug 2021 22:13:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	SICKD1

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:28:47

Generated On: 11 Aug 2021 22:13:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 11:20
Height (xxx.x)	163 cm
Weight (xxx.x)	70.0 kg
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:28:46

Generated On: 11 Aug 2021 22:13:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3272116

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Apr 2021 17:28:46

Generated On: 11 Aug 2021 22:13:55

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 FEB 2021

US3272116

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:28:47

Generated On: 11 Aug 2021 22:13:55

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

Visit date (dd MMM yyyy)	20 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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US3272116

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 17:28:47

Generated On: 11 Aug 2021 22:13:55

Date of updated informed consent (dd MMM yyyy) 20 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) 20 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 _____

US3272116

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:28:47

Generated On: 11 Aug 2021 22:13:55

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

Collection date (dd MMM yyyy)	20 JAN 2021
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Collection time (00:00-23:59)	10:53 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	20 JAN 2021 10:53
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US3272116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 17:28:47

Generated On: 11 Aug 2021 22:13:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00 - 23:59)

11:00

Collection Date and Time (derived)

20 JAN 2021 11:00

US3272116

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

365 of 2240

EAB) (1725)

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	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 _____	
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)	_____

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID	
Adverse event	NAUSEA
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)	16 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)	16 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2240

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	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 _____	
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)	_____

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID	
Adverse event	RHINORRHEA
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)	20 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2240

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	True
Concomitant Medication	False
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)	

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID	
Adverse event	NASAL CONGESTION
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)	20 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	True
Concomitant Medication	False
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)	_____

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID

Adverse event

BODY ACHES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

373 of 2240

EAB) (1725)

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	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 _____	
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)	_____

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID

Adverse event

MUSCLE ACHES
(GENERALIZED)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

375 of 2240

EAB) (1725)

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	
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)	

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

377 of 2240

EAB) (1725)

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	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	
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)	

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

AEID	
Adverse event	COUGH
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)	19 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)	22 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2240

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

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	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 _____	
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)	_____

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Generated On: 11 Aug 2021 22:13:55

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

Yes ☒

No ☐

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

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

Name of Medication ENSKYCE

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

382 of 2240

EAB) (1725)

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

	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)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

Name of Medication ZYZAL (LEVOCETIRIZINE
DIHYDROCHLORIDE)

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2240

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

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

If dose unit is Other, specify SPRAYS

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

386 of 2240

EAB) (1725)

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 14:56:50

Generated On: 11 Aug 2021 22:13:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

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

Generated On: 11 Aug 2021 22:13:55

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3272116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:13:55

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

US3272116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:13:55

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3272116 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272116

Form: Participant Creation

Generated On: 11 Aug 2021 22:13:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'US3272116'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:54:51

US3272116

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:48:30
	(b) (4)	

US3272116

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:54:52

US3272116

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4)	12 Aug 2020 22:48:30
	(b) (4)	

US3272116

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'SCRN'	System	12 Aug 2020 22:48:30

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:54:53

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:48:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 22:48:39
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	12 Aug 2020 22:48:39
User entered '28' reason for change: Data Entry Error	Kayla Flege (b) (4)	12 Aug 2020 22:48:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 17:52:38
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	12 Aug 2020 17:52:38
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'YEARS'	System	12 Aug 2020 22:48:39
User entered empty.	System	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered '28'	System	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Female (F)'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Ashley Bell (b) (4)	12 Aug 2020 17:52:38

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '12 Aug 2020'	Ashley Bell (b) (4)	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'Aug 2020'	System	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered '2020'	System	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Amendment 1 (1)'	Ashley Bell (b) (4)	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Ashley Bell (b) (4)	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Ashley Bell (b) (4)	12 Aug 2020 17:53:08

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:54:52

US3272116

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'I'	System	12 Aug 2020 17:53:12

US3272116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Ashley Bell (b) (4)	12 Aug 2020 17:53:12

US3272116

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:13:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 14:47:43
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:48:44
	(b) (4)	

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:49:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:49:21
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 14:48:45
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'un UNK 2018'	(b) (4), (b) (6)	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'Jan 2018'	System	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered '2018'	System	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered empty.	System	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered empty.	System	12 Oct 2020 14:48:09

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
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 21:00:13
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 20:49:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
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 12:40:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '12 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '11:40' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '11:40'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered '12 Aug 2020 11:40'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered '12 Aug 2020 11:40'	System	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '162.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '162.0' cm	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	
DataPoint set to visible.	System	12 Aug 2020 17:53:12

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '66.0' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '66.0' kg	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	
DataPoint set to visible.	System	12 Aug 2020 17:53:12

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered '25.14861'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered '25.1'	System	12 Aug 2020 22:49:41
DataPoint set to visible.	System	12 Aug 2020 17:53:12

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'kg/m2'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered 'kg/m2'	System	12 Aug 2020 22:49:41
DataPoint set to visible.	System	12 Aug 2020 17:53:12

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
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 21:00:16
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 20:49:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
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 12:40:52
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 12:40:52
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)	16 Sep 2020 15:21:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
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 20:55:37

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '78'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'bpm'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered 'bpm'	System	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '18'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'breaths/min'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered 'breaths/min'	System	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '116'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'mmHg'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered 'mmHg'	System	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 20:49:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:21:04
User entered '86'	Kayla Flege (b) (4)	12 Aug 2020 22:49:41
	(b) (4)	

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered 'mmHg'	System	25 Sep 2020 20:49:01
User entered empty.	System	16 Sep 2020 15:21:04
User entered 'mmHg'	System	12 Aug 2020 22:49:41

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07

US3272116

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07

US3272116

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 19:16:29
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:50:09
	(b) (4)	

US3272116

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:16:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 19:16:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:29:18
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:50:09
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:13:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:50:19
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Urine (URINE)'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Negative (NEGATIVE)'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:02:39
User closed query 'Per CDM: Thanks for your response however, if 'Was FSH sample collected?' is 'No' then collection date/collection time should not be completed. Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 14:36:08
Query 'Per CDM: Thanks for your response however, if 'Was FSH sample collected?' is 'No' then collection date/collection time should not be completed. Please review and amend accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:52:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:52:11
User opened query 'Per CDM: Thanks for your response however, if 'Was FSH sample collected?' is 'No' then collection date/collection time should not be completed. Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:04:15
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the 'collection date' and 'collection time' have both been recorded. Please review and update accordingly' canceled (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:03:35
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the 'collection date' and 'collection time' have both been recorded. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:02:34
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Per CDM: FSH sample collected is answered "Yes" but collection date is missing? Please provide.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:39:14
Query 'Per CDM: FSH sample collected is answered "Yes" but collection date is missing? Please provide.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:02:45
User opened query 'Per CDM: FSH sample collected is answered "Yes" but collection date is missing? Please provide.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 14:41:21
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:52:11
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 10:30:35
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'data correct' (Site from DM).		03 Sep 2020 18:44:00
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:05:26
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Per CDM: FSH sample collected is answered "Yes" but collection time is missing? Please provide.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:39:17
Query 'Per CDM: FSH sample collected is answered "Yes" but collection time is missing? Please provide.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:02:51
User opened query 'Per CDM: FSH sample collected is answered "Yes" but collection time is missing? Please provide.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 14:41:37
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:52:11
User entered '11:34'	Kayla Flege (b) (4)	12 Aug 2020 22:50:53
	(b) (4)	

US3272116

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User entered empty.	System	30 Sep 2020 18:52:11
User entered '12 Aug 2020 11:34'	System	12 Aug 2020 22:50:53

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:51:10
	(b) (4)	

US3272116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:22

US3272116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:51:22

US3272116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:22

US3272116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'VISIT1'	System	12 Aug 2020 22:51:22

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:59:25

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:54:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:54:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 16:59:25
User entered '103506' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:59:25

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:59:25

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

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 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:32

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

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 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:32

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:32

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:32

US3272116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:51:32

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:41:27
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).		03 Sep 2020 18:46:33
User entered missing code ND - Not Done; reason for change Data Entry Error		03 Sep 2020 18:46:22
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).		28 Aug 2020 17:21:01
User entered '162.0' cm	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
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)	16 Sep 2020 11:14:54
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'confirm update' (Site from DM).		10 Sep 2020 17:57:20
User entered missing code ND - Not Done; reason for change Data Entry Error		10 Sep 2020 17:57:17
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).		10 Sep 2020 12:41:39
User entered '66.0' kg	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:41:27
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).		03 Sep 2020 18:46:33
User entered missing code ND - Not Done; reason for change Data Entry Error		03 Sep 2020 18:46:22
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).		28 Aug 2020 17:21:01
User entered '162.0' cm	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
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)	16 Sep 2020 11:14:54
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'confirm update' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 17:57:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:57:17
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)	10 Sep 2020 12:41:39
User entered '66.0' kg	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '11:40'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered '12 Aug 2020 11:40'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '37.1' C	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '78'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'bpm'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '18'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'breaths/min'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '116'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'mmHg'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '86'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'mmHg'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:41:27
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).		03 Sep 2020 18:46:33
User entered missing code ND - Not Done; reason for change Data Entry Error		03 Sep 2020 18:46:22
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).		28 Aug 2020 17:21:01
User entered '162.0' cm	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
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)	16 Sep 2020 11:14:54
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'confirm update' (Site from DM).		10 Sep 2020 17:57:20
User entered missing code ND - Not Done; reason for change Data Entry Error		10 Sep 2020 17:57:17
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).		10 Sep 2020 12:41:39
User entered '66.0' kg	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	15 Aug 2020 14:05:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 14:05:08
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	12 Aug 2020 22:52:47
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
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)	19 Aug 2020 16:52:09
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 14:05:05
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).		12 Aug 2020 22:52:47
User entered '13:04'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered '12 Aug 2020 13:04'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '37.1' C	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '64'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'bpm'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '18'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'breaths/min'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '118'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'mmHg'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '76'	Kayla Flege (b) (4)	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'mmHg'	System	12 Aug 2020 22:52:47

US3272116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:52:57

US3272116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:52:57

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per CDM: Response noted however, no updates have been made? As Per CCG, If 'Screening' and 'Visit 1 Day 1' are done on the same day. Pregnancy test page should be marked as 'No' at V1D1. Please update as instructed. Thanks.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:13:42
User entered 'No (N)' reason for change: Data Entry Error		10 Nov 2020 20:21:33
Query 'Per CDM: Response noted however, no updates have been made? As Per CCG, If 'Screening' and 'Visit 1 Day 1' are done on the same day. Pregnancy test page should be marked as 'No' at V1D1. Please update as instructed. Thanks.' answered with 'updated' (Site from DM).		10 Nov 2020 20:20:52
User opened query 'Per CDM: Response noted however, no updates have been made? As Per CCG, If 'Screening' and 'Visit 1 Day 1' are done on the same day. Pregnancy test page should be marked as 'No' at V1D1. Please update as instructed. Thanks.' (Site from DM).		09 Nov 2020 17:02:56
User closed query 'Per CDM: Thanks for your response . As per CCG's , if Dosing (V1D1) and Screening Visits are done on the same day then only ONE Pregnancy form is required to be completed at 'Screening Visit' only. V1 D1 'Was the pregnancy test performed? should be marked as "NO". Please review and update.' (Site from DM).		09 Nov 2020 17:01:52
Query 'Per CDM: Thanks for your response . As per CCG's , if Dosing (V1D1) and Screening Visits are done on the same day then only ONE Pregnancy form is required to be completed at 'Screening Visit' only. V1 D1 'Was the pregnancy test performed? should be marked as "NO". Please review and update.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:52:44

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

Was the pregnancy test performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: Thanks for your response . As per CCG's , if Dosing (V1D1) and Screening Visits are done on the same day then only ONE Pregnancy form is required to be completed at 'Screening Visit' only. V1 D1 'Was the pregnancy test performed? should be marked as "NO". Please review and update.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:06:12
User closed query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).		29 Sep 2020 21:06:12
Query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' answered with 'data correct' (Site from DM).		16 Sep 2020 22:01:38
User opened query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).		16 Sep 2020 12:25:50
User closed query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).		16 Sep 2020 12:25:50
Query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' answered with 'data correct' (Site from DM).		03 Sep 2020 18:44:15
User opened query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).		02 Sep 2020 13:05:44
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:53:37

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:21:33
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:53:37
	(b) (4)	

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:21:33
User entered 'Urine (URINE)'	Kayla Flege (b) (4)	12 Aug 2020 22:53:37
	(b) (4)	

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:21:33
User entered 'Negative (NEGATIVE)'	Kayla Flege (b) (4)	12 Aug 2020 22:53:37

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:52:38
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:53:37

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:52:38
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:53:37

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:52:38
User entered '11:34'	Kayla Flege (b) (4)	12 Aug 2020 22:53:37

US3272116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered empty.	System	30 Sep 2020 18:52:38
User entered '12 Aug 2020 11:34'	System	12 Aug 2020 22:53:37

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	15 Aug 2020 15:17:01
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	15 Aug 2020 15:17:01
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	12 Aug 2020 17:53:31
User entered 'Yes (Y)'	Ashley Bell (b) (4)	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Ashley Bell (b) (4)	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12:30'	Ashley Bell (b) (4)	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered '12 Aug 2020 12:30'	System	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 15:17:01
User entered empty.	Ashley Bell (b) (4)	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'ONCE'	System	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:53:31

US3272116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:54:04

US3272116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:54:04

US3272116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '11:45'	Kayla Flege (b) (4)	12 Aug 2020 22:54:04

US3272116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered '12 Aug 2020 11:45'	System	12 Aug 2020 22:54:04

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:13:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Flege (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '11:41'	Kayla Flege (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered '12 Aug 2020 11:41'	System	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered empty.	System	12 Aug 2020 22:54:24

US3272116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:54:29

US3272116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:26:30
User entered 'I'	System	12 Aug 2020 22:54:29

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:05', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4b60cdb0-d85c-40f7-925b-ff7b9ae8ac9a'	System	12 Aug 2020 18:00:22
User entered 'Yes (Y)'	System	12 Aug 2020 18:00:22

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:09', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4b60cdb0-d85c-40f7-925b-ff7b9ae8ac9a'	System	12 Aug 2020 18:00:22
User entered '97.8'	System	12 Aug 2020 18:00:22

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:13', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4b60cdb0-d85c-40f7-925b-ff7b9ae8ac9a'	System	12 Aug 2020 18:00:22
User entered 'No (N)'	System	12 Aug 2020 18:00:22

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:17', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4b60cdb0-d85c-40f7-925b-ff7b9ae8ac9a'	System	12 Aug 2020 18:00:22
User entered '12 Aug 2020 13:00'	System	12 Aug 2020 18:00:22

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 12:50'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 15:20'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a34ae386-43c1-4d47-9def-877fa579131c'	System	13 Aug 2020 00:53:25
User entered 'Yes (Y)'	System	13 Aug 2020 00:53:25

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:09', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a34ae386-43c1-4d47-9def-877fa579131c' User entered '98.1'	System	13 Aug 2020 00:53:25
	System	13 Aug 2020 00:53:25

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a34ae386-43c1-4d47-9def-877fa579131c'	System	13 Aug 2020 00:53:25
User entered 'No (N)'	System	13 Aug 2020 00:53:25

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a34ae386-43c1-4d47-9def-877fa579131c'	System	13 Aug 2020 00:53:25
User entered '12 Aug 2020 19:53'	System	13 Aug 2020 00:53:25

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 16:15'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 2'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:43:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6a7e2076-c713-492a-9e8d-0f1547dd0d25'	System	13 Aug 2020 22:43:53
User entered 'Yes (Y)'	System	13 Aug 2020 22:43:53

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:43:45', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6a7e2076-c713-492a-9e8d-0f1547dd0d25'	System	13 Aug 2020 22:43:53
User entered '98.0'	System	13 Aug 2020 22:43:53

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:43:48', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6a7e2076-c713-492a-9e8d-0f1547dd0d25'	System	13 Aug 2020 22:43:53
User entered 'No (N)'	System	13 Aug 2020 22:43:53

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:43:51', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6a7e2076-c713-492a-9e8d-0f1547dd0d25'	System	13 Aug 2020 22:43:53
User entered '13 Aug 2020 17:43'	System	13 Aug 2020 22:43:53

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 3'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:42:36', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'cd928b66-7e8c-4dd6-a6cc-eee28d157650'	System	15 Aug 2020 01:42:49
User entered 'Yes (Y)'	System	15 Aug 2020 01:42:49

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:42:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'cd928b66-7e8c-4dd6-a6cc-eee28d157650'	System	15 Aug 2020 01:42:49
User entered '97.9'	System	15 Aug 2020 01:42:49

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:42:42', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'cd928b66-7e8c-4dd6-a6cc-eee28d157650'	System	15 Aug 2020 01:42:49
User entered 'No (N)'	System	15 Aug 2020 01:42:49

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:42:46', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'cd928b66-7e8c-4dd6-a6cc-eee28d157650'	System	15 Aug 2020 01:42:49
User entered '14 Aug 2020 20:42'	System	15 Aug 2020 01:42:49

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 4'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dbff203f-e1a9-412c-b211-71fd015c1a03'	System	16 Aug 2020 05:25:33
User entered 'Yes (Y)'	System	16 Aug 2020 05:25:33

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:24', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dbff203f-e1a9-412c-b211-71fd015c1a03'	System	16 Aug 2020 05:25:33
User entered '97.1'	System	16 Aug 2020 05:25:33

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dbff203f-e1a9-412c-b211-71fd015c1a03'	System	16 Aug 2020 05:25:33
User entered 'No (N)'	System	16 Aug 2020 05:25:33

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:30', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dbff203f-e1a9-412c-b211-71fd015c1a03'	System	16 Aug 2020 05:25:33
User entered '16 Aug 2020 00:25'	System	16 Aug 2020 05:25:33

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 5'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '70d91665-cfe5-440b-a4c3-1df3478ecc03'	System	17 Aug 2020 14:54:16
User entered 'Yes (Y)'	System	17 Aug 2020 14:54:16

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:07', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '70d91665-cfe5-440b-a4c3-1df3478ecc03'	System	17 Aug 2020 14:54:16
User entered '98.1'	System	17 Aug 2020 14:54:16

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:10', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '70d91665-cfe5-440b-a4c3-1df3478ecc03'	System	17 Aug 2020 14:54:16
User entered 'No (N)'	System	17 Aug 2020 14:54:16

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:13', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '70d91665-cfe5-440b-a4c3-1df3478ecc03'	System	17 Aug 2020 14:54:16
User entered '17 Aug 2020 09:54'	System	17 Aug 2020 14:54:16

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 6'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:13', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '9e9d7b75-5e2c-4721-9cc7-fe29df10ab2a'	System	18 Aug 2020 14:10:26
User entered 'Yes (Y)'	System	18 Aug 2020 14:10:26

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:16', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '9e9d7b75-5e2c-4721-9cc7-fe29df10ab2a' User entered '97.7'	System	18 Aug 2020 14:10:26
	System	18 Aug 2020 14:10:26

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:19', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '9e9d7b75-5e2c-4721-9cc7-fe29df10ab2a'	System	18 Aug 2020 14:10:26
User entered 'No (N)'	System	18 Aug 2020 14:10:26

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '9e9d7b75-5e2c-4721-9cc7-fe29df10ab2a'	System	18 Aug 2020 14:10:26
User entered '18 Aug 2020 09:10'	System	18 Aug 2020 14:10:26

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 7'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5d7143ae-b5f9-4438-acce-d8b59537abca'	System	12 Aug 2020 18:01:09
User entered 'None (1)'	System	12 Aug 2020 18:01:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:39', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5d7143ae-b5f9-4438-acce-d8b59537abca'	System	12 Aug 2020 18:01:09
User entered 'No (N)'	System	12 Aug 2020 18:01:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:42', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5d7143ae-b5f9-4438-acce-d8b59537abca'	System	12 Aug 2020 18:01:09
User entered 'No (N)'	System	12 Aug 2020 18:01:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:00:59', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5d7143ae-b5f9-4438-acce-d8b59537abca'	System	12 Aug 2020 18:01:09
User entered 'None (1)'	System	12 Aug 2020 18:01:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5d7143ae-b5f9-4438-acce-d8b59537abca'	System	12 Aug 2020 18:01:09
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 18:01:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 12:50'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 15:20'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:32', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '299007b7-d1ab-419c-9f16-9b149bb500b4'	System	13 Aug 2020 00:55:09
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:55:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:41', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '299007b7-d1ab-419c-9f16-9b149bb500b4'	System	13 Aug 2020 00:55:09
User entered 'No (N)'	System	13 Aug 2020 00:55:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:53:55', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '299007b7-d1ab-419c-9f16-9b149bb500b4'	System	13 Aug 2020 00:55:09
User entered 'No (N)'	System	13 Aug 2020 00:55:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:54:57', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '299007b7-d1ab-419c-9f16-9b149bb500b4'	System	13 Aug 2020 00:55:09
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:55:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '299007b7-d1ab-419c-9f16-9b149bb500b4'	System	13 Aug 2020 00:55:09
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:55:09

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 16:15'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 2'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:44:02', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5c86129-8c47-4d6a-9c67-2b7d0021569b'	System	13 Aug 2020 22:49:53
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 22:49:53

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:44:15', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5c86129-8c47-4d6a-9c67-2b7d0021569b'	System	13 Aug 2020 22:49:53
User entered 'No (N)'	System	13 Aug 2020 22:49:53

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:44:20', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5c86129-8c47-4d6a-9c67-2b7d0021569b'	System	13 Aug 2020 22:49:53
User entered 'Yes (Y)'	System	13 Aug 2020 22:49:53

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:49:35', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5c86129-8c47-4d6a-9c67-2b7d0021569b'	System	13 Aug 2020 22:49:53
User entered '40'	System	13 Aug 2020 22:49:53

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:49:41', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5c86129-8c47-4d6a-9c67-2b7d0021569b'	System	13 Aug 2020 22:49:53
User entered 'None (1)'	System	13 Aug 2020 22:49:53

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:49:49', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5c86129-8c47-4d6a-9c67-2b7d0021569b'	System	13 Aug 2020 22:49:53
User entered '13 Aug 2020 17:49'	System	13 Aug 2020 22:49:53

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 3'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:42:50', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a520fd87-3bf4-46ad-82c1-3cce22f63aae'	System	15 Aug 2020 01:43:15
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 01:43:15

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:42:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a520fd87-3bf4-46ad-82c1-3cce22f63aae'	System	15 Aug 2020 01:43:15
User entered 'No (N)'	System	15 Aug 2020 01:43:15

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a520fd87-3bf4-46ad-82c1-3cce22f63aae'	System	15 Aug 2020 01:43:15
User entered 'No (N)'	System	15 Aug 2020 01:43:15

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:06', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a520fd87-3bf4-46ad-82c1-3cce22f63aae'	System	15 Aug 2020 01:43:15
User entered 'None (1)'	System	15 Aug 2020 01:43:15

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:09', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a520fd87-3bf4-46ad-82c1-3cce22f63aae'	System	15 Aug 2020 01:43:15
User entered '14 Aug 2020 20:43'	System	15 Aug 2020 01:43:15

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 4'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:37', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9297896-b79e-45b0-91ed-41bd06abcf9f'	System	16 Aug 2020 05:25:51
User entered 'None (1)'	System	16 Aug 2020 05:25:51

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9297896-b79e-45b0-91ed-41bd06abcf9f'	System	16 Aug 2020 05:25:51
User entered 'No (N)'	System	16 Aug 2020 05:25:51

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:42', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9297896-b79e-45b0-91ed-41bd06abcf9f'	System	16 Aug 2020 05:25:51
User entered 'No (N)'	System	16 Aug 2020 05:25:51

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:45', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9297896-b79e-45b0-91ed-41bd06abcf9f'	System	16 Aug 2020 05:25:51
User entered 'None (1)'	System	16 Aug 2020 05:25:51

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:48', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9297896-b79e-45b0-91ed-41bd06abcf9f'	System	16 Aug 2020 05:25:51
User entered '16 Aug 2020 00:25'	System	16 Aug 2020 05:25:51

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 5'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:54', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd8228733-c159-4dd0-b9e7-e3e3d5e9699b'	System	17 Aug 2020 14:55:08
User entered 'None (1)'	System	17 Aug 2020 14:55:08

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:57', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd8228733-c159-4dd0-b9e7-e3e3d5e9699b'	System	17 Aug 2020 14:55:08
User entered 'No (N)'	System	17 Aug 2020 14:55:08

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:54:59', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd8228733-c159-4dd0-b9e7-e3e3d5e9699b'	System	17 Aug 2020 14:55:08
User entered 'No (N)'	System	17 Aug 2020 14:55:08

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:02', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd8228733-c159-4dd0-b9e7-e3e3d5e9699b'	System	17 Aug 2020 14:55:08
User entered 'None (1)'	System	17 Aug 2020 14:55:08

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd8228733-c159-4dd0-b9e7-e3e3d5e9699b'	System	17 Aug 2020 14:55:08
User entered '17 Aug 2020 09:55'	System	17 Aug 2020 14:55:08

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 6'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:24', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a39bf7a4-e8e9-4b11-8f59-8d1015813395'	System	18 Aug 2020 14:10:40
User entered 'None (1)'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a39bf7a4-e8e9-4b11-8f59-8d1015813395'	System	18 Aug 2020 14:10:40
User entered 'No (N)'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a39bf7a4-e8e9-4b11-8f59-8d1015813395'	System	18 Aug 2020 14:10:40
User entered 'No (N)'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:35', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a39bf7a4-e8e9-4b11-8f59-8d1015813395'	System	18 Aug 2020 14:10:40
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:37', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a39bf7a4-e8e9-4b11-8f59-8d1015813395'	System	18 Aug 2020 14:10:40
User entered '18 Aug 2020 09:10'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 7'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:12', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'None (0)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:15', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'None (0)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'None (0)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:41', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'None (0)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:46', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'None (0)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:49', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'None (0)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered 'No (N)'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T13:01:57', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ba3b3882-a34f-49e2-a843-d3e76d61f6e2'	System	12 Aug 2020 18:01:59
User entered '12 Aug 2020 13:01'	System	12 Aug 2020 18:01:59

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 12:50'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 15:20'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:08', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'None (0)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'None (0)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:24', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:37', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:41', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'None (0)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:45', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'None (0)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:49', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered 'No (N)'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-12T19:55:51', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c5268969-11e8-4c71-b69a-e2935147cc24'	System	13 Aug 2020 00:55:54
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:55:54

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '12 Aug 2020 16:15'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 2'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:49:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'None (0)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:49:55', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'None (0)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:50:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'No interference with activity (1)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:50:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'No interference with activity (1)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:50:06', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'None (0)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:50:08', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'None (0)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:50:11', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered 'No (N)'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-13T17:50:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2bc14ab-e4f4-47c4-8e53-955cde71573f'	System	13 Aug 2020 22:50:16
User entered '13 Aug 2020 17:50'	System	13 Aug 2020 22:50:16

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 3'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:13', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'None (0)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:15', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'None (0)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:19', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'None (0)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:24', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'None (0)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:26', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'None (0)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:28', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'None (0)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered 'No (N)'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-14T20:43:34', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd97c6de6-d6e8-461f-8b63-a738e703eff0'	System	15 Aug 2020 01:43:38
User entered '14 Aug 2020 20:43'	System	15 Aug 2020 01:43:38

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 4'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:52', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'None (0)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:54', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'None (0)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'None (0)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:25:59', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'None (0)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:26:02', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'None (0)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:26:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'None (0)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:26:07', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered 'No (N)'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-16T00:26:09', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd2b47757-841e-4131-be88-b87ae8ecb9a9'	System	16 Aug 2020 05:26:12
User entered '16 Aug 2020 00:26'	System	16 Aug 2020 05:26:12

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 5'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:08', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'None (0)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:10', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'None (0)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'None (0)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:17', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'None (0)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:19', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'None (0)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'None (0)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered 'No (N)'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-17T09:55:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e3d09b99-90ee-4a5f-be45-174f4bd0fb2b'	System	17 Aug 2020 14:55:34
User entered '17 Aug 2020 09:55'	System	17 Aug 2020 14:55:34

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 6'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:42', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'None (0)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:44', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'None (0)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:47', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'None (0)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:49', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'None (0)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:51', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'None (0)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'None (0)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered 'No (N)'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-18T09:10:58', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ed363a9a-bf7a-4205-af1b-d359cd41662c'	System	18 Aug 2020 14:11:02
User entered '18 Aug 2020 09:10'	System	18 Aug 2020 14:11:02

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 7'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	18 Aug 2020 14:10:40
User entered 'Day 8'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-19T13:31:48', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7bbc693b-a5a1-4edf-ab1e-40db1a68ddac'	System	19 Aug 2020 18:31:53
User entered 'No (N)'	System	19 Aug 2020 18:31:53

US3272116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-19T13:31:50', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7bbc693b-a5a1-4edf-ab1e-40db1a68ddac'	System	19 Aug 2020 18:31:53
User entered '19 Aug 2020 13:31'	System	19 Aug 2020 18:31:53

US3272116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	18 Aug 2020 14:10:40
User entered 'Day 8'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-19T13:31:54', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6e1760cf-079b-40dc-9d47-8f4d2c3bc934'	System	19 Aug 2020 18:31:58
User entered 'None (1)'	System	19 Aug 2020 18:31:58

US3272116

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-08-19T13:31:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6e1760cf-079b-40dc-9d47-8f4d2c3bc934'	System	19 Aug 2020 18:31:58
User entered '19 Aug 2020 13:31'	System	19 Aug 2020 18:31:58

US3272116

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 14:10:40

US3272116

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 14:10:40

US3272116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:25:58

US3272116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:25:58

US3272116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 21:25:58

US3272116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:25:58

US3272116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:26:03

US3272116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:07
User entered 'I'	System	28 Aug 2020 21:26:03

US3272116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:26:11

US3272116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:26:11

US3272116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 21:26:11

US3272116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:26:11

US3272116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:26:15

US3272116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:08
User entered 'I'	System	28 Aug 2020 21:26:15

US3272116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 22:21:12

US3272116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '02 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 22:21:12

US3272116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 22:21:12

US3272116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 22:21:12

US3272116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 22:21:14

US3272116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:40
User entered 'I'	System	02 Sep 2020 22:21:14

US3272116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 13:29:18

US3272116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 13:29:18

US3272116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 13:29:18

US3272116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'VISIT2'	System	14 Sep 2020 13:29:18

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User accepted default value 'Pre-Dose (PREDOSE)'		14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '07:48'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered '14 Sep 2020 07:48'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '36.9' C	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '67'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'bpm'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '16'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'breaths/min'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '115'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'mmHg'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '79'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'mmHg'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User accepted default value 'Post-Dose (POSTDOSE)'		14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '08:54'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered '14 Sep 2020 08:54'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '36.9' C	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '76'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'bpm'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '16'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'breaths/min'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '119'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'mmHg'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '82'	(b) (4), (b) (6)	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'mmHg'	System	14 Sep 2020 14:23:58

US3272116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:24:06

US3272116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:24:06

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Urine (URINE)'	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered empty.	System	14 Sep 2020 14:24:40

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '08:22'	(b) (4), (b) (6)	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered '14 Sep 2020 08:22'	System	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'ONCE'	System	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 13:29:59

US3272116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:25:06

US3272116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per GCL Lab Reconciliation: Antibody Mediated Immunogenicity: Sample dated 14-SEP-2020 is recorded under Visit 2 Day 29 in EDC; however, immuno sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, if not shipped, kindly ship the sample and provide the details also confirm the correct collection date of immuno sample for Visit 2 Day 29, else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 05:05:18
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 14:33:01
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'subject was unable to stay for full visit on 09sep2020 and subject came back 14sep2020 to complete visit' (Site from System).	(b) (4), (b) (6)	13 Mar 2021 01:36:58
Query 'Per GCL Lab Reconciliation: Antibody Mediated Immunogenicity: Sample dated 14-SEP-2020 is recorded under Visit 2 Day 29 in EDC; however, immuno sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, if not shipped, kindly ship the sample and provide the details also confirm the correct collection date of immuno sample for Visit 2 Day 29, else clarify.' answered with 'updated' (Site from DM).		13 Mar 2021 01:36:13
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Mar 2021 01:36:01
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 01:36:01

US3272116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody Mediated Immunogenicity: Sample dated 14-SEP-2020 is recorded under Visit 2 Day 29 in EDC; however, immuno sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, if not shipped, kindly ship the sample and provide the details also confirm the correct collection date of immuno sample for Visit 2 Day 29, else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:52:57
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 23:43:36
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Feb 2021 23:43:36
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 23:43:36
Amendment Manager: User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:48:33
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 15:32:57
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'her visit had to be split into two parts: first on the 9th of september, second on the 14th' (Site from System).		14 Sep 2020 14:25:31
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 14:25:06
User entered '09 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:25:06

US3272116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '09:18'	(b) (4), (b) (6)	14 Sep 2020 14:25:06

US3272116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered '09 Sep 2020 09:18'	System	13 Mar 2021 01:36:01
User entered '14 Sep 2020 09:18'	System	17 Feb 2021 23:43:36
User entered '09 Sep 2020 09:18'	System	14 Sep 2020 14:25:06

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:13:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 12:36:56
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'visit was split into two parts at patient's insistence; first half was on the 9th, second half on the 14th' (Site from System).		14 Sep 2020 14:26:03
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 14:25:43
User entered '09 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '09:06'	(b) (4), (b) (6)	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered '09 Sep 2020 09:06'	System	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered empty.	System	14 Sep 2020 14:25:43

US3272116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:26:07

US3272116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:45:00
User entered '1'	System	14 Sep 2020 14:26:07

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:54:12', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c3ef7339-a32a-4135-99eb-9ff269f8fb25'	System	14 Sep 2020 13:54:59
User entered 'Yes (Y)'	System	14 Sep 2020 13:54:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:54:50', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c3ef7339-a32a-4135-99eb-9ff269f8fb25' User entered '98.3'	System	14 Sep 2020 13:54:59
	System	14 Sep 2020 13:54:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:54:52', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c3ef7339-a32a-4135-99eb-9ff269f8fb25'	System	14 Sep 2020 13:54:59
User entered 'No (N)'	System	14 Sep 2020 13:54:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:54:55', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c3ef7339-a32a-4135-99eb-9ff269f8fb25'	System	14 Sep 2020 13:54:59
User entered '14 Sep 2020 08:54'	System	14 Sep 2020 13:54:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 08:42'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 11:12'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:13:23', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '76e48359-ec5f-4ced-b631-c76bb6bef771'	System	15 Sep 2020 01:13:36
User entered 'Yes (Y)'	System	15 Sep 2020 01:13:36

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:13:26', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '76e48359-ec5f-4ced-b631-c76bb6bef771'	System	15 Sep 2020 01:13:36
User entered '97.9'	System	15 Sep 2020 01:13:36

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:13:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '76e48359-ec5f-4ced-b631-c76bb6bef771'	System	15 Sep 2020 01:13:36
User entered 'No (N)'	System	15 Sep 2020 01:13:36

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:13:32', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '76e48359-ec5f-4ced-b631-c76bb6bef771'	System	15 Sep 2020 01:13:36
User entered '14 Sep 2020 20:13'	System	15 Sep 2020 01:13:36

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 12:07'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 2'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '786bc3b1-a709-4e2b-85f0-673e488b1dcd'	System	16 Sep 2020 10:26:05
User entered 'Yes (Y)'	System	16 Sep 2020 10:26:05

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:36', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '786bc3b1-a709-4e2b-85f0-673e488b1dcd' User entered '97.0'	System	16 Sep 2020 10:26:05
	System	16 Sep 2020 10:26:05

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '786bc3b1-a709-4e2b-85f0-673e488b1dcd'	System	16 Sep 2020 10:26:05
User entered 'No (N)'	System	16 Sep 2020 10:26:05

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:43', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '786bc3b1-a709-4e2b-85f0-673e488b1dcd'	System	16 Sep 2020 10:26:05
User entered '16 Sep 2020 05:25'	System	16 Sep 2020 10:26:05

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 3'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '447f28fc-3325-42b6-9343-f241d4269703'	System	17 Sep 2020 12:12:42
User entered 'Yes (Y)'	System	17 Sep 2020 12:12:42

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:35', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '447f28fc-3325-42b6-9343-f241d4269703'	System	17 Sep 2020 12:12:42
User entered '97.0'	System	17 Sep 2020 12:12:42

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:37', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '447f28fc-3325-42b6-9343-f241d4269703'	System	17 Sep 2020 12:12:42
User entered 'No (N)'	System	17 Sep 2020 12:12:42

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '447f28fc-3325-42b6-9343-f241d4269703'	System	17 Sep 2020 12:12:42
User entered '17 Sep 2020 07:12'	System	17 Sep 2020 12:12:42

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 4'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 5'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d4ab24e-47f3-4811-89f6-11b89330a3c8'	System	19 Sep 2020 13:10:44
User entered 'Yes (Y)'	System	19 Sep 2020 13:10:44

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:36', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d4ab24e-47f3-4811-89f6-11b89330a3c8'	System	19 Sep 2020 13:10:44
User entered '97.0'	System	19 Sep 2020 13:10:44

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:38', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d4ab24e-47f3-4811-89f6-11b89330a3c8'	System	19 Sep 2020 13:10:44
User entered 'No (N)'	System	19 Sep 2020 13:10:44

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d4ab24e-47f3-4811-89f6-11b89330a3c8'	System	19 Sep 2020 13:10:44
User entered '19 Sep 2020 08:10'	System	19 Sep 2020 13:10:44

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 6'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb3baf6-d9ef-4e24-b8d8-6f82f0bb7aba'	System	20 Sep 2020 11:19:52
User entered 'No (N)'	System	20 Sep 2020 11:19:52

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:43', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb3baf6-d9ef-4e24-b8d8-6f82f0bb7aba'	System	20 Sep 2020 11:19:52
User entered 'No (N)'	System	20 Sep 2020 11:19:52

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:46', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb3baf6-d9ef-4e24-b8d8-6f82f0bb7aba'	System	20 Sep 2020 11:19:52
User entered '20 Sep 2020 06:19'	System	20 Sep 2020 11:19:52

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 7'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:42:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5b3d5de7-744f-421f-bb29-be2e8da8894c'	System	21 Sep 2020 15:43:07
User entered 'No (N)'	System	21 Sep 2020 15:43:07

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:42:58', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5b3d5de7-744f-421f-bb29-be2e8da8894c'	System	21 Sep 2020 15:43:07
User entered 'No (N)'	System	21 Sep 2020 15:43:07

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5b3d5de7-744f-421f-bb29-be2e8da8894c'	System	21 Sep 2020 15:43:07
User entered '21 Sep 2020 10:43'	System	21 Sep 2020 15:43:07

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'edb8bd12-708d-48f8-bd2b-73802fcf1a54'	System	14 Sep 2020 13:55:25
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 13:55:25

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:11', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'edb8bd12-708d-48f8-bd2b-73802fcf1a54'	System	14 Sep 2020 13:55:25
User entered 'No (N)'	System	14 Sep 2020 13:55:25

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:16', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'edb8bd12-708d-48f8-bd2b-73802fcf1a54'	System	14 Sep 2020 13:55:25
User entered 'No (N)'	System	14 Sep 2020 13:55:25

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'edb8bd12-708d-48f8-bd2b-73802fcf1a54'	System	14 Sep 2020 13:55:25
User entered 'None (1)'	System	14 Sep 2020 13:55:25

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:22', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'edb8bd12-708d-48f8-bd2b-73802fcf1a54'	System	14 Sep 2020 13:55:25
User entered '14 Sep 2020 08:55'	System	14 Sep 2020 13:55:25

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 08:42'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 11:12'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:13:55', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7fa10855-9aad-4fde-b526-694ca194bd3b'	System	15 Sep 2020 01:16:19
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	15 Sep 2020 01:16:19

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:14:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7fa10855-9aad-4fde-b526-694ca194bd3b'	System	15 Sep 2020 01:16:19
User entered 'No (N)'	System	15 Sep 2020 01:16:19

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:14:07', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7fa10855-9aad-4fde-b526-694ca194bd3b'	System	15 Sep 2020 01:16:19
User entered 'Yes (Y)'	System	15 Sep 2020 01:16:19

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:15:57', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7fa10855-9aad-4fde-b526-694ca194bd3b'	System	15 Sep 2020 01:16:19
User entered '29'	System	15 Sep 2020 01:16:19

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7fa10855-9aad-4fde-b526-694ca194bd3b'	System	15 Sep 2020 01:16:19
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 01:16:19

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:16', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7fa10855-9aad-4fde-b526-694ca194bd3b'	System	15 Sep 2020 01:16:19
User entered '14 Sep 2020 20:16'	System	15 Sep 2020 01:16:19

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 12:07'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 2'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:50', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ab759693-631b-4bc3-a9bd-c143644abe73'	System	16 Sep 2020 10:26:27
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 10:26:27

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ab759693-631b-4bc3-a9bd-c143644abe73'	System	16 Sep 2020 10:26:27
User entered 'No (N)'	System	16 Sep 2020 10:26:27

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:25:59', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ab759693-631b-4bc3-a9bd-c143644abe73'	System	16 Sep 2020 10:26:27
User entered 'No (N)'	System	16 Sep 2020 10:26:27

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ab759693-631b-4bc3-a9bd-c143644abe73'	System	16 Sep 2020 10:26:27
User entered 'None (1)'	System	16 Sep 2020 10:26:27

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:05', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ab759693-631b-4bc3-a9bd-c143644abe73'	System	16 Sep 2020 10:26:27
User entered '16 Sep 2020 05:26'	System	16 Sep 2020 10:26:27

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 3'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:46', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb945db-bb44-47bc-a260-28db17165c74'	System	17 Sep 2020 12:13:03
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 12:13:03

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:48', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb945db-bb44-47bc-a260-28db17165c74'	System	17 Sep 2020 12:13:03
User entered 'No (N)'	System	17 Sep 2020 12:13:03

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:50', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb945db-bb44-47bc-a260-28db17165c74'	System	17 Sep 2020 12:13:03
User entered 'No (N)'	System	17 Sep 2020 12:13:03

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:12:57', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb945db-bb44-47bc-a260-28db17165c74'	System	17 Sep 2020 12:13:03
User entered 'None (1)'	System	17 Sep 2020 12:13:03

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'deb945db-bb44-47bc-a260-28db17165c74'	System	17 Sep 2020 12:13:03
User entered '17 Sep 2020 07:13'	System	17 Sep 2020 12:13:03

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 4'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 5'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:44', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd730e945-11d3-493c-b7bd-eac65dd54a11'	System	19 Sep 2020 13:10:55
User entered 'None (1)'	System	19 Sep 2020 13:10:55

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:47', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd730e945-11d3-493c-b7bd-eac65dd54a11'	System	19 Sep 2020 13:10:55
User entered 'No (N)'	System	19 Sep 2020 13:10:55

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:49', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd730e945-11d3-493c-b7bd-eac65dd54a11'	System	19 Sep 2020 13:10:55
User entered 'No (N)'	System	19 Sep 2020 13:10:55

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:51', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd730e945-11d3-493c-b7bd-eac65dd54a11'	System	19 Sep 2020 13:10:55
User entered 'None (1)'	System	19 Sep 2020 13:10:55

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd730e945-11d3-493c-b7bd-eac65dd54a11'	System	19 Sep 2020 13:10:55
User entered '19 Sep 2020 08:10'	System	19 Sep 2020 13:10:55

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 6'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:51', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ee590ac2-1f97-4127-b88c-59a583d5858d'	System	20 Sep 2020 11:20:07
User entered 'None (1)'	System	20 Sep 2020 11:20:07

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:54', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ee590ac2-1f97-4127-b88c-59a583d5858d'	System	20 Sep 2020 11:20:07
User entered 'No (N)'	System	20 Sep 2020 11:20:07

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ee590ac2-1f97-4127-b88c-59a583d5858d'	System	20 Sep 2020 11:20:07
User entered 'No (N)'	System	20 Sep 2020 11:20:07

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:19:59', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ee590ac2-1f97-4127-b88c-59a583d5858d'	System	20 Sep 2020 11:20:07
User entered 'None (1)'	System	20 Sep 2020 11:20:07

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:02', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ee590ac2-1f97-4127-b88c-59a583d5858d' User entered '20 Sep 2020 06:20'	System	20 Sep 2020 11:20:07
	System	20 Sep 2020 11:20:07

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 7'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:05', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ce5b8499-7c40-46f4-bf94-007a2ab9ea47'	System	21 Sep 2020 15:43:24
User entered 'None (1)'	System	21 Sep 2020 15:43:24

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:07', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ce5b8499-7c40-46f4-bf94-007a2ab9ea47'	System	21 Sep 2020 15:43:24
User entered 'No (N)'	System	21 Sep 2020 15:43:24

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:10', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ce5b8499-7c40-46f4-bf94-007a2ab9ea47'	System	21 Sep 2020 15:43:24
User entered 'No (N)'	System	21 Sep 2020 15:43:24

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:12', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ce5b8499-7c40-46f4-bf94-007a2ab9ea47'	System	21 Sep 2020 15:43:24
User entered 'None (1)'	System	21 Sep 2020 15:43:24

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:19', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'ce5b8499-7c40-46f4-bf94-007a2ab9ea47'	System	21 Sep 2020 15:43:24
User entered '21 Sep 2020 10:43'	System	21 Sep 2020 15:43:24

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered 'None (0)'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:28', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered 'None (0)'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:30', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered 'None (0)'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c' User entered 'None (0)'	System	14 Sep 2020 13:55:41
	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:33', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered 'None (0)'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:34', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered 'None (0)'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:37', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered 'No (N)'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T08:55:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f40486a6-444f-40d2-bd85-6db983bf747c'	System	14 Sep 2020 13:55:41
User entered '14 Sep 2020 08:55'	System	14 Sep 2020 13:55:41

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 08:42'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 11:12'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:25', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:30', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:35', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:38', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'None (0)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:48', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:51', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered 'No (N)'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-14T20:16:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '27fd3c0a-453c-4927-8a32-c56e13cd7398'	System	15 Sep 2020 01:16:56
User entered '14 Sep 2020 20:16'	System	15 Sep 2020 01:16:56

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '14 Sep 2020 12:07'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 2'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:11', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'None (0)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'Some interference with activity (2)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:23', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'None (0)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:28', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'None (0)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'None (0)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:38', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'No interference with activity (1)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:41', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered 'No (N)'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-16T05:26:44', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'dda122a0-7403-4444-901a-ac124ec503ff'	System	16 Sep 2020 10:27:07
User entered '16 Sep 2020 05:26'	System	16 Sep 2020 10:27:07

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 3'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'None (0)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:07', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'None (0)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:10', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'None (0)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:11', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'None (0)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:13', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'None (0)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'None (0)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:17', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered 'No (N)'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-17T07:13:19', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '14ee4430-d0da-4f5c-b4fd-106bd34e9102'	System	17 Sep 2020 12:13:21
User entered '17 Sep 2020 07:13'	System	17 Sep 2020 12:13:21

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 4'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 5'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:57', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'None (0)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:10:59', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'None (0)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:11:16', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'No interference with activity (1)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:11:19', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'None (0)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:11:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'None (0)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:11:24', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'None (0)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:11:26', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered 'No (N)'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-19T08:11:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '223eed56-326e-4f59-99cf-ffda37d4e54c'	System	19 Sep 2020 13:11:33
User entered '19 Sep 2020 08:11'	System	19 Sep 2020 13:11:33

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 6'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:06', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'None (0)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:08', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'None (0)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'Some interference with activity (2)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'None (0)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:23', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'None (0)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:26', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'None (0)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered 'No (N)'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-20T06:20:32', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'd61edb34-47fc-453c-a983-2be6308d9ef4'	System	20 Sep 2020 11:20:34
User entered '20 Sep 2020 06:20'	System	20 Sep 2020 11:20:34

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	14 Sep 2020 13:29:59
User entered 'Day 7'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:23', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'None (0)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:25', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'None (0)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'None (0)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:30', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'None (0)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:32', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'None (0)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:34', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'None (0)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:37', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered 'No (N)'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-09-21T10:43:39', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e226a085-cd91-4046-afa6-59962e9c0d53'	System	21 Sep 2020 15:43:43
User entered '21 Sep 2020 10:43'	System	21 Sep 2020 15:43:43

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:29:59

US3272116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:29:59

US3272116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:49:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:24:39

US3272116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:49:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 20:24:39

US3272116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:49:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 20:24:39

US3272116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:49:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:24:39

US3272116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:49:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 20:24:42

US3272116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:49:59
User entered 'I'	System	21 Sep 2020 20:24:42

US3272116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:09:16

US3272116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 20:09:53
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	05 Oct 2020 20:09:53
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 20:09:53
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 20:09:16
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:09:16

US3272116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 20:09:16

US3272116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:09:16

US3272116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:09:59

US3272116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:40
User entered 'I'	System	05 Oct 2020 20:09:59

US3272116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:15:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:10:10

US3272116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:15:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:10:10

US3272116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:15:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 20:10:10

US3272116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:15:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:10:10

US3272116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:15:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:10:14

US3272116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:15:48
User entered 'I'	System	05 Oct 2020 20:10:14

US3272116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:55:22

US3272116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:55:22

US3272116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 14:55:22

US3272116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered 'VISIT3'	System	12 Oct 2020 14:55:22

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '09:05'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered '12 Oct 2020 09:05'	System	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '37.1' C	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '74'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered 'bpm'	System	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '16'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered 'breaths/min'	System	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '119'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered 'mmHg'	System	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '86'	(b) (4), (b) (6)	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered 'mmHg'	System	12 Oct 2020 14:56:07

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04

US3272116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04

US3272116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:56:15

US3272116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:56:15

US3272116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:56:34

US3272116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:56:34

US3272116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '09:14'	(b) (4), (b) (6)	12 Oct 2020 14:56:34

US3272116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered '12 Oct 2020 09:14'	System	12 Oct 2020 14:56:34

US3272116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:56:40

US3272116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:16:04
User entered '1'	System	12 Oct 2020 14:56:40

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 64'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-10-12T06:27:25', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d150963-91f3-401a-8677-bfafa2793a67'	System	12 Oct 2020 11:27:34
User entered 'No (N)'	System	12 Oct 2020 11:27:34

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-10-12T06:27:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d150963-91f3-401a-8677-bfafa2793a67'	System	12 Oct 2020 11:27:34
User entered 'No (N)'	System	12 Oct 2020 11:27:34

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-10-12T06:27:32', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7d150963-91f3-401a-8677-bfafa2793a67'	System	12 Oct 2020 11:27:34
User entered '12 Oct 2020 06:27:32'	System	12 Oct 2020 11:27:34

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 71'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you been exposed to someone with 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)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:06:04
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 78'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-10-28T10:03:24', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '11979d36-80e5-48cf-98f1-becddd449a53'	System	28 Oct 2020 15:03:33
User entered 'No (N)'	System	28 Oct 2020 15:03:33

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-10-28T10:03:27', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '11979d36-80e5-48cf-98f1-becddd449a53'	System	28 Oct 2020 15:03:33
User entered 'No (N)'	System	28 Oct 2020 15:03:33

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-10-28T10:03:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '11979d36-80e5-48cf-98f1-becddd449a53'	System	28 Oct 2020 15:03:33
User entered '28 Oct 2020 10:03:29'	System	28 Oct 2020 15:03:33

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 92'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-09T16:21:29', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'bead3c07-1e1b-4f75-9e7b-e3013e140e86'	System	09 Nov 2020 22:21:37
User entered 'No (N)'	System	09 Nov 2020 22:21:37

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-09T16:21:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'bead3c07-1e1b-4f75-9e7b-e3013e140e86'	System	09 Nov 2020 22:21:37
User entered 'No (N)'	System	09 Nov 2020 22:21:37

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-09T16:21:33', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'bead3c07-1e1b-4f75-9e7b-e3013e140e86'	System	09 Nov 2020 22:21:37
User entered '09 Nov 2020 16:21:33'	System	09 Nov 2020 22:21:37

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered 'Day 99'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-17T16:47:04', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5c4626eb-be9b-479c-aad7-0f4e1cfb1659'	System	17 Nov 2020 22:47:16
User entered 'No (N)'	System	17 Nov 2020 22:47:16

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-17T16:47:09', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5c4626eb-be9b-479c-aad7-0f4e1cfb1659'	System	17 Nov 2020 22:47:16
User entered 'No (N)'	System	17 Nov 2020 22:47:16

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-17T16:47:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5c4626eb-be9b-479c-aad7-0f4e1cfb1659' User entered '17 Nov 2020 16:47:14'	System	17 Nov 2020 22:47:16
	System	17 Nov 2020 22:47:16

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 17:53:31

US3272116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:47:14
Data entry locked.	System	12 Aug 2020 17:53:31
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 17:53:31

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2020-11-24T11:44:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c618cfb1-eeac-4e71-abc8-c8b06c6a019f'	System	24 Nov 2020 17:44:26
User entered 'No (N)'	System	24 Nov 2020 17:44:26

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2020-11-24T11:44:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c618cfb1-eeac-4e71-abc8-c8b06c6a019f'	System	24 Nov 2020 17:44:26
User entered 'No (N)'	System	24 Nov 2020 17:44:26

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-24T11:44:23', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'c618cfb1-eeac-4e71-abc8-c8b06c6a019f'	System	24 Nov 2020 17:44:26
User entered '24 Nov 2020 11:44:23'	System	24 Nov 2020 17:44:26

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2020-11-27T08:41:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '61845734-d70e-4c15-905c-e6a90dca276d'	System	27 Nov 2020 14:42:04
User entered 'No (N)'	System	27 Nov 2020 14:42:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2020-11-27T08:41:58', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '61845734-d70e-4c15-905c-e6a90dca276d'	System	27 Nov 2020 14:42:04
User entered 'No (N)'	System	27 Nov 2020 14:42:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-11-27T08:42:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '61845734-d70e-4c15-905c-e6a90dca276d'	System	27 Nov 2020 14:42:04
User entered '27 Nov 2020 08:42:00'	System	27 Nov 2020 14:42:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2020-12-11T00:04:54', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9449ed4-b2da-454a-8149-f5473395a328'	System	11 Dec 2020 06:05:03
User entered 'No (N)'	System	11 Dec 2020 06:05:03

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2020-12-11T00:04:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9449ed4-b2da-454a-8149-f5473395a328'	System	11 Dec 2020 06:05:03
User entered 'No (N)'	System	11 Dec 2020 06:05:03

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-12-11T00:04:58', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'e9449ed4-b2da-454a-8149-f5473395a328'	System	11 Dec 2020 06:05:03
User entered '11 Dec 2020 00:04:58'	System	11 Dec 2020 06:05:03

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2020-12-19T22:16:23', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '0f06a4b0-1c02-48f9-89ec-6f293ed5395e'	System	20 Dec 2020 04:16:47
User entered 'No (N)'	System	20 Dec 2020 04:16:47

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2020-12-19T22:16:26', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '0f06a4b0-1c02-48f9-89ec-6f293ed5395e'	System	20 Dec 2020 04:16:47
User entered 'No (N)'	System	20 Dec 2020 04:16:47

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2020-12-19T22:16:44', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '0f06a4b0-1c02-48f9-89ec-6f293ed5395e' User entered '19 Dec 2020 22:16:44'	System	20 Dec 2020 04:16:47
	System	20 Dec 2020 04:16:47

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-01-01T17:22:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'b62921fa-fa0a-42cd-8b68-4225abf3ad79'	System	02 Jan 2021 00:22:33
User entered 'No (N)'	System	02 Jan 2021 00:22:33

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-01-01T17:22:17', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'b62921fa-fa0a-42cd-8b68-4225abf3ad79'	System	02 Jan 2021 00:22:33
User entered 'No (N)'	System	02 Jan 2021 00:22:33

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-01-01T17:22:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'b62921fa-fa0a-42cd-8b68-4225abf3ad79'	System	02 Jan 2021 00:22:33
User entered '01 Jan 2021 17:22:18'	System	02 Jan 2021 00:22:33

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-01-10T07:55:16', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5725aa8b-42a2-4e89-8177-614d7e04b4c8'	System	10 Jan 2021 13:55:41
User entered 'No (N)'	System	10 Jan 2021 13:55:41

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-01-10T07:55:20', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5725aa8b-42a2-4e89-8177-614d7e04b4c8'	System	10 Jan 2021 13:55:41
User entered 'No (N)'	System	10 Jan 2021 13:55:41

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-01-10T07:55:38', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '5725aa8b-42a2-4e89-8177-614d7e04b4c8'	System	10 Jan 2021 13:55:41
User entered '10 Jan 2021 07:55:38'	System	10 Jan 2021 13:55:41

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-01-15T11:07:56', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '72309629-714d-4303-8ed9-f12c1210cd97'	System	15 Jan 2021 17:08:06
User entered 'No (N)'	System	15 Jan 2021 17:08:06

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-01-15T11:07:58', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '72309629-714d-4303-8ed9-f12c1210cd97'	System	15 Jan 2021 17:08:06
User entered 'No (N)'	System	15 Jan 2021 17:08:06

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-01-15T11:08:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '72309629-714d-4303-8ed9-f12c1210cd97'	System	15 Jan 2021 17:08:06
User entered '15 Jan 2021 11:08:00'	System	15 Jan 2021 17:08:06

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-01-22T13:30:15', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '87f1f714-180e-468b-9182-6cf05fd7ef41'	System	22 Jan 2021 19:30:24
User entered 'No (N)'	System	22 Jan 2021 19:30:24

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-01-22T13:30:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '87f1f714-180e-468b-9182-6cf05fd7ef41'	System	22 Jan 2021 19:30:24
User entered 'No (N)'	System	22 Jan 2021 19:30:24

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-01-22T13:30:21', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '87f1f714-180e-468b-9182-6cf05fd7ef41'	System	22 Jan 2021 19:30:24
User entered '22 Jan 2021 13:30:21'	System	22 Jan 2021 19:30:24

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-01-29T09:03:55', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '83846736-cfa6-45b6-93cc-4b8606273772'	System	29 Jan 2021 15:04:09
User entered 'No (N)'	System	29 Jan 2021 15:04:09

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-01-29T09:03:58', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '83846736-cfa6-45b6-93cc-4b8606273772'	System	29 Jan 2021 15:04:09
User entered 'No (N)'	System	29 Jan 2021 15:04:09

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-01-29T09:04:05', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '83846736-cfa6-45b6-93cc-4b8606273772'	System	29 Jan 2021 15:04:09
User entered '29 Jan 2021 09:04:05'	System	29 Jan 2021 15:04:09

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-02-05T11:57:28', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '8ec2aef1-75f6-4b86-8f26-8346201d8464'	System	05 Feb 2021 17:57:35
User entered 'No (N)'	System	05 Feb 2021 17:57:35

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-02-05T11:57:30', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '8ec2aef1-75f6-4b86-8f26-8346201d8464'	System	05 Feb 2021 17:57:35
User entered 'No (N)'	System	05 Feb 2021 17:57:35

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-05T11:57:31', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '8ec2aef1-75f6-4b86-8f26-8346201d8464'	System	05 Feb 2021 17:57:35
User entered '05 Feb 2021 11:57:31'	System	05 Feb 2021 17:57:35

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-02-12T18:49:11', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a7a414fd-0987-4da9-b82b-25d9c41fb628'	System	13 Feb 2021 00:49:21
User entered 'No (N)'	System	13 Feb 2021 00:49:21

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-02-12T18:49:14', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a7a414fd-0987-4da9-b82b-25d9c41fb628'	System	13 Feb 2021 00:49:21
User entered 'No (N)'	System	13 Feb 2021 00:49:21

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-12T18:49:18', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'a7a414fd-0987-4da9-b82b-25d9c41fb628'	System	13 Feb 2021 00:49:21
User entered '12 Feb 2021 18:49:18'	System	13 Feb 2021 00:49:21

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-02-19T08:42:40', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered 'Yes (Y)'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-02-19T08:42:44', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered 'No (N)'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:42:49', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered 'Yes (Y)'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '1'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '1'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '1'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:03', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '0'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:39', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:46', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered 'No (N)'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-19T08:43:53', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7201dc3f-4909-4489-807d-9e244e87979b'	System	19 Feb 2021 14:44:05
User entered '19 Feb 2021 08:43:53'	System	19 Feb 2021 14:44:05

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-02-27T13:46:43-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4dcbd8e2-fed7-479d-a310-741aa666c2c5' User entered 'No (N)'	System	27 Feb 2021 19:46:51
	System	27 Feb 2021 19:46:51

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-02-27T13:46:46-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4dcbd8e2-fed7-479d-a310-741aa666c2c5'	System	27 Feb 2021 19:46:51
User entered 'No (N)'	System	27 Feb 2021 19:46:51

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-27T13:46:48-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '4dcbd8e2-fed7-479d-a310-741aa666c2c5'	System	27 Feb 2021 19:46:51
User entered '27 Feb 2021 13:46:48'	System	27 Feb 2021 19:46:51

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-03-07T10:13:40-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7ee98a10-657a-4d79-a21d-382fb76bd247'	System	07 Mar 2021 16:13:47
User entered 'No (N)'	System	07 Mar 2021 16:13:47

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-03-07T10:13:43-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7ee98a10-657a-4d79-a21d-382fb76bd247'	System	07 Mar 2021 16:13:47
User entered 'No (N)'	System	07 Mar 2021 16:13:47

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-03-07T10:13:44-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '7ee98a10-657a-4d79-a21d-382fb76bd247'	System	07 Mar 2021 16:13:47
User entered '07 Mar 2021 10:13:44'	System	07 Mar 2021 16:13:47

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-04-02T09:27:52-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'bcf21e4a-73c6-4882-938d-203c4d6c95b6' User entered 'No (N)'	System	02 Apr 2021 14:28:02
	System	02 Apr 2021 14:28:02

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-04-02T09:27:54-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'bcf21e4a-73c6-4882-938d-203c4d6c95b6'	System	02 Apr 2021 14:28:02
User entered 'No (N)'	System	02 Apr 2021 14:28:02

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-04-02T09:27:56-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'bcf21e4a-73c6-4882-938d-203c4d6c95b6'	System	02 Apr 2021 14:28:02
User entered '02 Apr 2021 09:27:56'	System	02 Apr 2021 14:28:02

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-04-09T15:11:20-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '31957f77-820e-4369-905c-864db8765a76' User entered 'No (N)'	System	09 Apr 2021 20:11:30
	System	09 Apr 2021 20:11:30

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-04-09T15:11:22-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '31957f77-820e-4369-905c-864db8765a76'	System	09 Apr 2021 20:11:30
User entered 'No (N)'	System	09 Apr 2021 20:11:30

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-04-09T15:11:24-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '31957f77-820e-4369-905c-864db8765a76' User entered '09 Apr 2021 15:11:24'	System	09 Apr 2021 20:11:30
	System	09 Apr 2021 20:11:30

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-04-16T11:53:28-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6ad23604-4a1d-4d13-abe8-fdd8722b6601'	System	16 Apr 2021 16:53:37
User entered 'No (N)'	System	16 Apr 2021 16:53:37

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-04-16T11:53:30-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6ad23604-4a1d-4d13-abe8-fdd8722b6601'	System	16 Apr 2021 16:53:37
User entered 'No (N)'	System	16 Apr 2021 16:53:37

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-04-16T11:53:33-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '6ad23604-4a1d-4d13-abe8-fdd8722b6601'	System	16 Apr 2021 16:53:37
User entered '16 Apr 2021 11:53:33'	System	16 Apr 2021 16:53:37

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-04-25T15:46:26-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f3fbdfc2-bfed-43e5-8f6f-345882fb99f5'	System	25 Apr 2021 20:46:44
User entered 'No (N)'	System	25 Apr 2021 20:46:44

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-04-25T15:46:27-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f3fbdfc2-bfed-43e5-8f6f-345882fb99f5'	System	25 Apr 2021 20:46:44
User entered 'No (N)'	System	25 Apr 2021 20:46:44

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-04-25T15:46:40-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'f3fbdfc2-bfed-43e5-8f6f-345882fb99f5'	System	25 Apr 2021 20:46:44
User entered '25 Apr 2021 15:46:40'	System	25 Apr 2021 20:46:44

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[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 (fa41f7e5c6aa571f)', Time: '2021-04-30T06:05:05-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'fad6f7d2-0e9f-4e37-ad12-7287c17edc70'	System	30 Apr 2021 11:05:12
User entered 'No (N)'	System	30 Apr 2021 11:05:12

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

Have you been exposed to someone with 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 (fa41f7e5c6aa571f)', Time: '2021-04-30T06:05:08-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'fad6f7d2-0e9f-4e37-ad12-7287c17edc70'	System	30 Apr 2021 11:05:12
User entered 'No (N)'	System	30 Apr 2021 11:05:12

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-04-30T06:05:10-05:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: 'fad6f7d2-0e9f-4e37-ad12-7287c17edc70'	System	30 Apr 2021 11:05:12
User entered '30 Apr 2021 06:05:10'	System	30 Apr 2021 11:05:12

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:06:04

US3272116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:06:04
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:06:04

US3272116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:13:55

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 09:06:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-27T13:46:53-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '79a43f6a-82f2-4d78-ae5b-87a6a788c951'	System	27 Feb 2021 19:46:59
User entered 'No (N)'	System	27 Feb 2021 19:46:59

US3272116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:13:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:06:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fa41f7e5c6aa571f)', Time: '2021-02-27T13:46:57-06:00', User OID: 'PatientReportedOutcome (US3272116)', ODM File OID: '79a43f6a-82f2-4d78-ae5b-87a6a788c951' User entered '27 Feb 2021 13:46:57'	System	27 Feb 2021 19:46:59
	System	27 Feb 2021 19:46:59

US3272116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Nov 2020 20:17:28

US3272116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '7 Nov 2020'	(b) (4), (b) (6)	07 Nov 2020 20:17:28

US3272116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Nov 2020 20:17:28

US3272116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:17:28

US3272116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Nov 2020 20:17:44

US3272116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:27
User entered 'I'	System	07 Nov 2020 20:17:44

US3272116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:22:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 17:24:04

US3272116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:22:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '10 Dec 2020'	(b) (4), (b) (6)	13 Jan 2021 17:24:04

US3272116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:22:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 17:24:04

US3272116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:22:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 17:24:04

US3272116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:22:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 17:24:10

US3272116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:22:26
User entered 'I'	System	13 Jan 2021 17:24:10

US3272116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:27:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 17:25:15

US3272116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:27:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '13 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 17:25:15

US3272116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:27:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 17:25:15

US3272116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:27:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 17:25:15

US3272116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:27:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 17:25:19

US3272116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:27:16
User entered 'I'	System	13 Jan 2021 17:25:19

US3272116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:42:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 22:45:30

US3272116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:42:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '10 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 22:45:30

US3272116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:42:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 22:45:30

US3272116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:42:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 22:45:30

US3272116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:42:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 22:45:36

US3272116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:42:24
User entered 'I'	System	12 Feb 2021 22:45:36

US3272116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 23:24:21

US3272116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 23:24:21

US3272116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Mar 2021 23:24:21

US3272116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered 'VISIT4'	System	18 Mar 2021 23:24:21

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered empty.	System	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered empty.	System	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered empty.	System	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered empty.	System	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered empty.	System	31 Mar 2021 00:03:10

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19

US3272116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19

US3272116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 23:24:30

US3272116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 23:24:30

US3272116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 23:24:44

US3272116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 23:24:44

US3272116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered '13:30'	(b) (4), (b) (6)	18 Mar 2021 23:24:44

US3272116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered '18 Mar 2021 13:30'	System	18 Mar 2021 23:24:44

US3272116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:29:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 23:24:50

US3272116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:19
User entered 'I'	System	18 Mar 2021 23:24:50

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:55

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 20:54:44

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:55

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '10:20'	(b) (4), (b) (6)	19 Feb 2021 20:54:44

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:57
User entered '19 Feb 2021 10:20'	System	19 Feb 2021 20:54:44

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:55

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	19 Feb 2021 20:54:44

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 20:54:44

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '16 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 20:56:58

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '17 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 21:07:38

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '18 Feb 2020'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 19:35:47
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 21:08:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '99'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '97.8' F	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Feb 2021 21:09:55

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 5 (Day 5)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '20 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered missing code ND - Not Done.	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	23 Feb 2021 17:18:30

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 6 (Day 6)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '21 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	23 Feb 2021 18:13:42
User entered empty.	System	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:13:42
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 7 (Day 7)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '22 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	23 Feb 2021 18:15:02
User entered empty.	System	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '97.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered 'Mild (Mild)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:15:02
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Day 8 (Day 8)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '23 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '98'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User entered '%'	System	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '97.1' F	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Mild (Mild)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)'	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 19:35:47
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 19:35:47
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:20:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'None (None)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 19:35:47
User entered empty.	Whitney West (b) (4)	23 Feb 2021 17:43:51

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:55

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:03
User entered '0'	System	23 Feb 2021 23:11:29

US3272116

Folder: Covid-19 Assessment 19 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:13:55

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Mar 2021 01:33:24

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 3 (Day 3)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 3, EDC Sample date is 19feb2021, however in PPD Central Lab sample dated 21feb2021 (Accession # 1F640023184) is reported. Hence please confirm correct date of collection for Day 3 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:27:01
User entered '21 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 01:34:47
Query 'Per GCL Lab Reconciliation: Saliva : For Day 3, EDC Sample date is 19feb2021, however in PPD Central Lab sample dated 21feb2021 (Accession # 1F640023184) is reported. Hence please confirm correct date of collection for Day 3 and update EDC or PPD Central lab.' answered with 'date in edc correct' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:34:16
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 3, EDC Sample date is 19feb2021, however in PPD Central Lab sample dated 21feb2021 (Accession # 1F640023184) is reported. Hence please confirm correct date of collection for Day 3 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 14:18:13
User entered '19 Feb 2021' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 23:12:20
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 5 (Day 5)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:13:55

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 21FEB2021, however in PPD Central Lab sample dated 23FEB2021 (Accession # 1F634252432) is reported. Hence please confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:27:17
Query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 21FEB2021, however in PPD Central Lab sample dated 23FEB2021 (Accession # 1F634252432) is reported. Hence please confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:35:13
User entered '23 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 01:35:05
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 21FEB2021, however in PPD Central Lab sample dated 23FEB2021 (Accession # 1F634252432) is reported. Hence please confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:47:39
User entered '21 Feb 2021' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 23:12:20
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 7 (Day 7)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Whitney West (b) (4)	23 Feb 2021 23:12:20
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 23:11:44
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 9 (Day 9)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'NA (COVID-19 Negative) (NA)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 14 (Day 14)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'NA (COVID-19 Negative) (NA)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 21 (Day 21)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'NA (COVID-19 Negative) (NA)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:13:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User accepted default value 'Day 28 (Day 28)'	Whitney West (b) (4) (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:13:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'NA (COVID-19 Negative) (NA)'	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	Whitney West (b) (4)	23 Feb 2021 23:09:43

US3272116

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 21:11:46

US3272116

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:11:46

US3272116

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 17:30:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Feb 2021 21:11:46

US3272116

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:12
User entered 'SICKD1'	System	19 Feb 2021 21:11:46

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '11:20'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User entered '19 Feb 2021 11:20'	System	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '163' cm	(b) (4), (b) (6)	19 Feb 2021 21:13:07
DataPoint set to visible.	System	19 Feb 2021 21:11:46

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '70.0' kg	(b) (4), (b) (6)	19 Feb 2021 21:13:07
DataPoint set to visible.	System	19 Feb 2021 21:11:46

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '97.8' F	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '78'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User entered 'bpm'	System	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '16'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User entered 'breaths/min'	System	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '109'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User entered 'mmHg'	System	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '73'	(b) (4), (b) (6)	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18
User entered 'mmHg'	System	19 Feb 2021 21:13:07

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18

US3272116

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:18

US3272116

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 21:13:16

US3272116

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:13:16

US3272116

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:13:55

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 21:13:26

US3272116

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:13:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:13:26

US3272116

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:56:24

US3272116

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:56:24

US3272116

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[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 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Jan 2021 20:56:24

US3272116

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 20:56:24

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[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 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:22:25

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User closed query 'PER CDM: 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 field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:34:55
Query 'PER CDM: 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 field.' answered with 'Data corrected' (Site from DM).		08 Apr 2021 19:31:53
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error		08 Apr 2021 19:31:32
User opened query 'PER CDM: 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 field.' (Site from DM).		08 Apr 2021 12:09:41
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:22:25

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User entered empty.	System	20 Jan 2021 20:57:19

US3272116

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User entered empty.	System	20 Jan 2021 20:57:19

US3272116

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:57:30

US3272116

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:57:30

US3272116

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '10:53'	(b) (4), (b) (6)	20 Jan 2021 20:57:30

US3272116

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User entered '20 Jan 2021 10:53'	System	20 Jan 2021 20:57:30

US3272116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:57:50

US3272116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:57:50

US3272116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:28:55
User entered '11:00'	(b) (4), (b) (6)	20 Jan 2021 20:57:50

US3272116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:32:19
User entered '20 Jan 2021 11:00'	System	20 Jan 2021 20:57:50

US3272116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:13:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:06:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	23 Feb 2021 19:57:03
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:54:36

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Per DM CLR: Please review this AE and the following AEs: #2 NAUSEA, #3 RHINORRHEA, #4 NASAL CONGESTION, #5 BODY ACHES, #6 MUSCLE ACHES, #7 FATIGUE, & #8 COUGH as these have overlapping start/end dates. Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:03:05
Query 'Per DM CLR: Please review this AE and the following AEs: #2 NAUSEA, #3 RHINORRHEA, #4 NASAL CONGESTION, #5 BODY ACHES, #6 MUSCLE ACHES, #7 FATIGUE, & #8 COUGH as these have overlapping start/end dates. Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify. ' answered with 'per protocol all symptoms are to be listed separately' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:30:17
User opened query 'Per DM CLR: Please review this AE and the following AEs: #2 NAUSEA, #3 RHINORRHEA, #4 NASAL CONGESTION, #5 BODY ACHES, #6 MUSCLE ACHES, #7 FATIGUE, & #8 COUGH as these have overlapping start/end dates. Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:10:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 19:59:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 19:59:03
Data point term sent to Coder	System	23 Feb 2021 19:58:17
User entered 'Sore throat'	Whitney West (b) (4)	23 Feb 2021 19:58:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

1901 of 2240

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User entered empty.	System	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '22 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User entered empty.	System	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User entered '0'	System	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40
User entered 'I'	System	23 Feb 2021 19:58:04

US3272116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:40

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:01:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:01:15
Data point term sent to Coder	System	23 Feb 2021 20:00:19
User entered 'Nausea'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User entered empty.	System	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User entered empty.	System	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User entered '0'	System	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45
User entered 'I'	System	23 Feb 2021 20:00:06

US3272116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:27:45

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:18:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:18:04
Data point term sent to Coder	System	23 Feb 2021 20:01:40
User entered 'Rhinorrhea'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '20 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 20:04:38
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Feb 2021 20:04:38
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 20:00:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 20:04:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 20:04:44
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 20:04:44
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 20:00:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 20:04:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[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 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 20:04:44

US3272116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 20:00:52

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:02:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:02:13
Data point term sent to Coder	System	23 Feb 2021 20:01:41
User entered 'Nasal congestion'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 20:01:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 20:01:41
User entered '20 Feb 2021' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 20:01:41
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 20:01:25
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	23 Feb 2021 20:01:49
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 14:01:28
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'NA.' (Site from System).	Whitney West (b) (4)	23 Feb 2021 20:03:21
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 20:01:49
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 20:01:25
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 20:01:25
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Per CDM: Outcome is recorded as Recovered/Resolved, but Ongoing is recorded a yes and End Date is missing. Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 14:57:53
Query 'Per CDM: Outcome is recorded as Recovered/Resolved, but Ongoing is recorded a yes and End Date is missing. Please review and update accordingly else clarify.' answered with 'Updated. Original typo. ' (Site from DM).	Whitney West (b) (4)	24 Feb 2021 17:57:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Feb 2021 17:57:18
User opened query 'Per CDM: Outcome is recorded as Recovered/Resolved, but Ongoing is recorded a yes and End Date is missing. Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 14:05:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[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 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 20:01:25

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:06:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:06:04
Data point term sent to Coder	System	23 Feb 2021 20:05:48
User entered 'Body aches'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User entered empty.	System	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User entered empty.	System	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User entered '0'	System	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35
User entered 'I'	System	23 Feb 2021 20:05:44

US3272116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:35

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:03:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGTT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	13 Mar 2021 01:31:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Mar 2021 01:31:50
Data point term sent to Coder	System	13 Mar 2021 01:31:09
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:31:04
Coding entries removed.	(b) (4), (b) (6)	13 Mar 2021 01:30:56
User entered 'MUSCLE ACHES (generalized)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 01:30:56
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:10:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGTT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:10:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:10:05

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	23 Feb 2021 20:08:53
User entered 'Muscle aches'	Whitney West (b) (4)	23 Feb 2021 20:08:02
	(b) (4)	

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User entered empty.	System	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User entered empty.	System	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User entered '0'	System	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27
User entered 'I'	System	23 Feb 2021 20:08:02

US3272116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:27

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:10:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:10:08
Data point term sent to Coder	System	23 Feb 2021 20:08:53
User entered 'Fatigue'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User entered empty.	System	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '16 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User entered empty.	System	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User entered '0'	System	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11
User entered 'I'	System	23 Feb 2021 20:08:52

US3272116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:11

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:11:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 20:11:04
Data point term sent to Coder	System	23 Feb 2021 20:09:56
User entered 'Cough'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '19 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User entered empty.	System	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '22 Feb 2021'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User entered empty.	System	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Whitney West (b) (4)	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User entered '0'	System	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02
User entered 'I'	System	23 Feb 2021 20:09:48

US3272116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:02

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:06:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:47:30
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'med taken listed in con meds' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 21:48:23
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 07:09:49
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	12 Aug 2020 22:54:43

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: DESOGESTREL;ETHINYLESTRADIOL, PRODUCTSYNONYM: ENSKYCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 10:09:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 10:09:19
Data point term sent to Coder	System	12 Aug 2020 22:56:00
User entered 'Enskyce'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 20:36:56
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Contraception'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'I'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'tablet (TABLET)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'once daily (QD)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Oral (ORAL)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '12 Aug 2020'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:25:57
User entered 'Yes (Y)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:25:57
User entered empty.	Kayla Flege (b) (4)	12 Aug 2020 22:55:46
	(b) (4)	

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User entered '1'	System	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User entered '1'	System	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:13:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:43
User entered '804 (804)'	System	12 Aug 2020 22:55:46

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:06:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:06:54
Data point term sent to Coder	System	12 Oct 2020 14:51:52
User entered 'Zyzal (Levocetirizine dihydrochloride)'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 20:38:35
User entered 'Yes (Y)'		12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '5'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'un UNK 2018'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:13:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 14:51:11

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 14:54:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 14:54:28
Data point term sent to Coder	System	12 Oct 2020 14:53:54
User entered 'Flonase'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 20:39:14
User entered 'Yes (Y)'		12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Seasonal allergies'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '2'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'sprays'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'un UNK 2018'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:13:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 14:53:20

US3272116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:13:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:56:52
User entered 'No (N)'	Kayla Flege (b) (4)	12 Aug 2020 22:55:55