

US3572116 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:19:24

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US3572116

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Participant ID

US3572116

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

US3572116

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Date of Birth (MMM yyyy)	(b) (6) 2002
Age	18
Age Units	YEARS
Age (Derived)	18
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:33:56

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Condition	ORAL PAIN
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:20
Height (xxx.x)	61 in
Weight (xxx.x)	161.7 lb
BMI (xxx.x)	30.61683 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	27 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:33:56

Generated On: 10 Jun 2021 08:19:24

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:33:56

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 108856

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 <input type="radio"/>
	No <input checked="" type="radio"/>
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Severe obesity (body mass index > or = 40kg/m2)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Diabetes (Type I, Type 2, or gestational)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Liver Disease	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Human Immunodeficiency Virus (HIV) infection	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

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)	27 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:19
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 11:49

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	11:25 (24 HR)
Collection date and time (derived)	27 AUG 2020 11:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:28	27 AUG 2020 11:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:28

PC Open Date & Time

27 AUG 2020 12:09

PC Close Date & Time

27 AUG 2020 14:39

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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 98.8 °F

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

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

PC Time Stamp	27 AUG 2020 16:36
PC Open Date & Time	27 AUG 2020 15:34
PC Close Date & Time	28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

99.1 °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

28 AUG 2020 16:50

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 14:50

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 30 AUG 2020 18:48

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

98.9 °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

31 AUG 2020 12:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

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 01 SEP 2020 22:45

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 13:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

27 AUG 2020 12:29

PC Open Date & Time

27 AUG 2020 12:09

PC Close Date & Time

27 AUG 2020 14:39

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

27 AUG 2020 16:38

PC Open Date & Time

27 AUG 2020 15:34

PC Close Date & Time

28 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

28 AUG 2020 16:50

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

29 AUG 2020 14:49

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

30 AUG 2020 18:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

31 AUG 2020 12:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

01 SEP 2020 22:45

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

02 SEP 2020 13:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 12:29
PC Open Date & Time	27 AUG 2020 12:09
PC Close Date & Time	27 AUG 2020 14:39

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 16:38
PC Open Date & Time	27 AUG 2020 15:34
PC Close Date & Time	28 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 16:51
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 14:50
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 18:48
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:13
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

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EAB) (1725)

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:46
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:11
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3572116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 SEP 2020

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

Comments VM @ 1:04P

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:09

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

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)	25 SEP 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:19
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:16
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3572116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	25 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)	

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 10:46 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 10:46

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

What was the frequency of the study treatment dosing? ONCE

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

US3572116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	10:21 (24 HR)
Collection date and time (derived)	25 SEP 2020 10:21

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:15	25 SEP 2020 10:15
Nasopharyngeal Swab 2	No		

US3572116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 11:13

PC Open Date & Time

25 SEP 2020 11:06

PC Close Date & Time

25 SEP 2020 13:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 00:52

PC Open Date & Time

25 SEP 2020 14:31

PC Close Date & Time

26 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

98.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

26 SEP 2020 17:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

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

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

PC Time Stamp	28 SEP 2020 17:39
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

98.9 °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

29 SEP 2020 23:18

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 00:09

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

25 SEP 2020 11:14

PC Open Date & Time

25 SEP 2020 11:06

PC Close Date & Time

25 SEP 2020 13:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

26 SEP 2020 00:53

PC Open Date & Time

25 SEP 2020 14:31

PC Close Date & Time

26 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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 ☐

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

30

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)**

30

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 17:37

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

28 SEP 2020 17:40

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

29 SEP 2020 23:18

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

01 OCT 2020 00:10

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 11:14
PC Open Date & Time	25 SEP 2020 11:06
PC Close Date & Time	25 SEP 2020 13:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 00:53
PC Open Date & Time	25 SEP 2020 14:31
PC Close Date & Time	26 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:37
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 17:41
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 23:19
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

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EAB) (1725)

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 00:10
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3572116

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3572116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:10

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:42
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3572116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	08:58 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:58

US3572116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:11:11

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 00:14:03

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 00:06:16

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 00:01:53
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 00:01:32
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

05 DEC 2020 01:27:35

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 03:10:13
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 14:52:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

02 JAN 2021 13:08:54

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	True
Congestion	False
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	10 JAN 2021 01:27:50
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

20 JAN 2021 09:24:42

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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	30 JAN 2021 13:59:14
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

08 FEB 2021 10:50:38

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

15 FEB 2021 19:47:09

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

20 FEB 2021 00:01:43

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 18:24:22
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

13 MAR 2021 11:23:17

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 11:28:00

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 00:02:11

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

26 APR 2021 12:40:21

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 <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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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"/>

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2022 00:01
Patient Cloud Close Date & Time	02 NOV 2022 23:59

US3572116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:19:24

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		03 MAR 2021 18:24:13

US3572116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:14:28

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:14:28

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3572116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

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.

US3572116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3572116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572116

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572116

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Date of Contact	3 SEP 2020
Time of Contact	18:00
Date and Time of Contact (derived)	3 SEP 2020 18:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3572116

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3572116

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:24

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5	<input type="checkbox"/>
	Amendment 6 or later	<input type="checkbox"/>
Date of unblinding (<i>dd MMM yyyy</i>)		
Participant randomization assignment	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
Actual Dose 1	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Actual Dose 2	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Will participant receive mRNA-1273?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Placebo Only Flag		
Continuing with mRNA-1273		

US3572116

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<input type="text"/>
Collection time (<i>00:00-23:59</i>)	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:24

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection Date and Time (derived)

US3572116

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:40:32

Generated On: 10 Jun 2021 08:19:24

AEID	
Adverse event	DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:40:32

Generated On: 10 Jun 2021 08:19:24

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:40:32

Generated On: 10 Jun 2021 08:19:24

AEID	USA-US091-2021-MRNA-1273-P30 1000020
Adverse event	SUICIDE ATTEMPT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 APR 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)	23 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 APR 2021
Hospital Discharge Date (dd MMM yyyy)	23 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:40:32

Generated On: 10 Jun 2021 08:19:24

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	2ND SUICIDE ATTEMPT. 1ST IN MARCH BUT SUBJECT DOESN'T REMEMBER EXACT DATES.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

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

Yes ☒

No ☐

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

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication SLEEP

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

	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) _____		
Start date completely unknown		True
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"/>

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 SEP 2020
Was this medication taken for solicited event?		Yes <input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication ORAJEL

Prophylaxis Yes ☐
No ☒

Indication ORAL PAIN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication VITAMIN

Dose per administration 2500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

Name of Medication ASENAPINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTS ALCOHOL
CRAVINGS

Dose per administration UNKNOWN

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:07:11

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:29:22

Generated On: 10 Jun 2021 08:19:24

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3572116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:19:24

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

US3572116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:19:24

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 ☐

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 15:47:35

Generated On: 10 Jun 2021 08:19:24

SAEID	USA-US091-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 15:47:35

Generated On: 10 Jun 2021 08:19:24

SAEID	USA-US091-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	27/APR/2021 08:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 15:47:35

Generated On: 10 Jun 2021 08:19:24

SAEID	USA-US091-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/APR/2021 07:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3572116 (Prod: Laguna Clinical Research Associates)

US3572116

Form: Participant Creation

Generated On: 10 Jun 2021 08:19:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'US3572116'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:09:37

US3572116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:25:21

US3572116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:09:38

US3572116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:25:21

US3572116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'SCRN'	System	27 Aug 2020 16:25:21

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered (b) (6) 2002'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:09:39

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'YEARS'	System	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '18'	System	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Female (F)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'I'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:02

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'Aug 2020'	System	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '2020'	System	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Amendment 2 (2)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:23

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:09:38

US3572116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'l'	System	27 Aug 2020 16:26:33

US3572116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 16:26:33

US3572116

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:19:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:48:16

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 04:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 04:49:39
Data point term sent to Coder	System	02 Oct 2020 04:48:41
User entered 'Anemia'	Alisha Lutat (b) (4)	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'UN UNK 2014'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'Jan 2014'	System	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '2014'	System	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered empty.	System	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered empty.	System	02 Oct 2020 04:48:40

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
Query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).	(b) (4) (u) (4), (b) (6)	09 Nov 2020 13:03:52
User opened query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:07:34
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 04:50:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 04:50:42
Data point term sent to Coder	System	02 Oct 2020 04:49:42
User entered 'Bipolar Disorder'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'UN UNK 2016'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'UN UNK 2017'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'Jan 2016'	System	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '2016'	System	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'Jan 2017'	System	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '2017'	System	02 Oct 2020 04:49:13

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue signs and symptoms, PT: Oral pain, LLT: Oral pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 23:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 23:15:43
Data point term sent to Coder	System	15 Feb 2021 23:14:41
User entered 'Oral Pain'	(b) (4), (b) (6)	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'un UNK 2019'	(b) (4) (u) (4), (b) (6)	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) (u) (4), (b) (6)	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) (u) (4), (b) (6)	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) (u) (4), (b) (6)	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'Jan 2019'	System	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '2019'	System	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered empty.	System	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered empty.	System	15 Feb 2021 23:14:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '11:20'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '27 Aug 2020 11:20'	System	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '61' in	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:50:27
DataPoint set to visible.	(b) (4) System	27 Aug 2020 16:26:33

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '161.7' lb	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:50:27
DataPoint set to visible.	(b) (4) System	27 Aug 2020 16:26:33

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered '30.61683'	System	02 Oct 2020 04:50:27
DataPoint set to visible.	System	27 Aug 2020 16:26:33

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'kg/m2'	System	02 Oct 2020 04:50:27
DataPoint set to visible.	System	27 Aug 2020 16:26:33

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'bpm'	System	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'breaths/min'	System	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'mmHg'	System	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered 'mmHg'	System	02 Oct 2020 04:50:27

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08

US3572116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08

US3572116

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:42

US3572116

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:50:42

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:24

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:00

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Urine (URINE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Negative (NEGATIVE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User entered empty.	System	02 Oct 2020 04:51:21

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:52:04

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:52:04

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:08
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:33:56
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:52:04

US3572116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:46:46

US3572116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:46:46

US3572116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:46:46

US3572116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'VISIT1'	System	02 Oct 2020 04:46:46

US3572116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Per CDM: Patient was randomized into the study. Please complete all Visit 1 Day 1 forms.' (Site from DM).	(b) (4)	
Query 'Per CDM: Patient was randomized into the study. Please complete all Visit 1 Day 1 forms.' answered with 'All visit 1 day forms have been updated ' (Site from DM).	(u) (4), (b) (6)	09 Dec 2020 14:08:23
User opened query 'Per CDM: Patient was randomized into the study. Please complete all Visit 1 Day 1 forms.' (Site from DM).	Alisha Lutat (b) (4)	09 Dec 2020 01:27:21
User entered '27 AUG 2020'	(b) (4)	
	(b) (4), (b) (6)	07 Sep 2020 11:20:02
	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:19:41

US3572116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '108856'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:19:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:19:41

US3572116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete this section of the form.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:34:19
User entered 'No (N)'	Alisha Lutat (b) (4)	02 Oct 2020 04:47:37
	(b) (4)	
	Alisha Lutat (b) (4)	02 Oct 2020 04:47:03
	(b) (4)	
User opened query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 12:16:57
	(6)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:47:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:47:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:47:03

US3572116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:47:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 04:47:03
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:47:53
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:14:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	02 Oct 2020 04:55:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:28
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Oct 2020 04:55:11
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '11:20'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Aug 2020 11:20'	System	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '98.1' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '74'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'bpm'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'breaths/min'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '119'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '62'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	02 Oct 2020 04:55:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:28
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Oct 2020 04:55:11
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '12:19'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Aug 2020 12:19'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '98.1' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '73'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'bpm'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'breaths/min'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '98'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (u) (4), (b) (6)	06 Oct 2020 07:44:13
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:45
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Oct 2020 04:55:11
User entered '59'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	02 Oct 2020 04:55:11

US3572116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:47:18

US3572116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:47:18

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Per CDM: Please consider entering data as No. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 05:59:46
Query 'Per CDM: Please consider entering data as No. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 08:03:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 08:02:58
User opened query 'Per CDM: Please consider entering data as No. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:27:02
User entered empty.	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered empty.	System	02 Oct 2020 04:56:01

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4)	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '11:49'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Aug 2020 11:49'	System	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'ONCE'	System	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 17:26:09

US3572116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:37

US3572116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:37

US3572116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '11:25'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:56:37

US3572116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Aug 2020 11:25'	System	02 Oct 2020 04:56:37

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '11:28'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Aug 2020 11:28'	System	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered empty.	System	02 Oct 2020 04:57:05

US3572116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 17:54:02

US3572116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'I'	System	10 Sep 2020 17:54:02

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:28:27', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fc6af160-eb5f-44e3-b980-42dedcb7e1d6'	System	27 Aug 2020 17:28:40
User entered 'Yes (Y)'	System	27 Aug 2020 17:28:40

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:28:32', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fc6af160-eb5f-44e3-b980-42dedcb7e1d6'	System	27 Aug 2020 17:28:40
User entered '98.1'	System	27 Aug 2020 17:28:40

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:28:35', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fc6af160-eb5f-44e3-b980-42dedcb7e1d6'	System	27 Aug 2020 17:28:40
User entered 'No (N)'	System	27 Aug 2020 17:28:40

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:28:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fc6af160-eb5f-44e3-b980-42dedcb7e1d6'	System	27 Aug 2020 17:28:40
User entered '27 Aug 2020 12:28'	System	27 Aug 2020 17:28:40

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Aug 2020 14:39'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:36:04', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e10567bb-dee2-434d-8881-d232548a2b1f'	System	27 Aug 2020 21:36:29
User entered 'Yes (Y)'	System	27 Aug 2020 21:36:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:36:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e10567bb-dee2-434d-8881-d232548a2b1f' User entered '98.8'	System	27 Aug 2020 21:36:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:36:23', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e10567bb-dee2-434d-8881-d232548a2b1f'	System	27 Aug 2020 21:36:29
User entered 'No (N)'	System	27 Aug 2020 21:36:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:36:27', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e10567bb-dee2-434d-8881-d232548a2b1f'	System	27 Aug 2020 21:36:29
User entered '27 Aug 2020 16:36'	System	27 Aug 2020 21:36:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Aug 2020 15:34'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 2'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd1d3c4d3-49e5-493a-9707-9d7ce113e527'	System	28 Aug 2020 21:50:35
User entered 'Yes (Y)'	System	28 Aug 2020 21:50:35

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:21', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd1d3c4d3-49e5-493a-9707-9d7ce113e527'	System	28 Aug 2020 21:50:35
User entered '99.1'	System	28 Aug 2020 21:50:35

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:24', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd1d3c4d3-49e5-493a-9707-9d7ce113e527'	System	28 Aug 2020 21:50:35
User entered 'No (N)'	System	28 Aug 2020 21:50:35

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:30', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd1d3c4d3-49e5-493a-9707-9d7ce113e527'	System	28 Aug 2020 21:50:35
User entered '28 Aug 2020 16:50'	System	28 Aug 2020 21:50:35

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 3'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3d09b07-8080-46ac-9c90-34041db75fd8'	System	29 Aug 2020 19:50:29
User entered 'Yes (Y)'	System	29 Aug 2020 19:50:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:20', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3d09b07-8080-46ac-9c90-34041db75fd8'	System	29 Aug 2020 19:50:29
User entered '98.8'	System	29 Aug 2020 19:50:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:23', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3d09b07-8080-46ac-9c90-34041db75fd8'	System	29 Aug 2020 19:50:29
User entered 'No (N)'	System	29 Aug 2020 19:50:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:25', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3d09b07-8080-46ac-9c90-34041db75fd8'	System	29 Aug 2020 19:50:29
User entered '29 Aug 2020 14:50'	System	29 Aug 2020 19:50:29

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 4'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '4ecd19d3-83e7-47cc-8704-44b4c19fd326'	System	30 Aug 2020 23:48:27
User entered 'No (N)'	System	30 Aug 2020 23:48:27

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:18', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '4ecd19d3-83e7-47cc-8704-44b4c19fd326'	System	30 Aug 2020 23:48:27
User entered 'No (N)'	System	30 Aug 2020 23:48:27

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:23', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '4ecd19d3-83e7-47cc-8704-44b4c19fd326'	System	30 Aug 2020 23:48:27
User entered '30 Aug 2020 18:48'	System	30 Aug 2020 23:48:27

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 5'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:12:04', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '23c52714-31f7-4fe5-b636-05e7202dad03'	System	31 Aug 2020 17:20:38
User entered 'Yes (Y)'	System	31 Aug 2020 17:20:38

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:12:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '23c52714-31f7-4fe5-b636-05e7202dad03'	System	31 Aug 2020 17:20:38
User entered '98.9'	System	31 Aug 2020 17:20:38

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:12:55', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '23c52714-31f7-4fe5-b636-05e7202dad03'	System	31 Aug 2020 17:20:38
User entered 'No (N)'	System	31 Aug 2020 17:20:38

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '23c52714-31f7-4fe5-b636-05e7202dad03'	System	31 Aug 2020 17:20:38
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:20:38

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 6'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '4b91adf3-bcbc-4104-a23f-704a074ef469'	System	02 Sep 2020 03:45:46
User entered 'No (N)'	System	02 Sep 2020 03:45:46

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:40', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '4b91adf3-bcbc-4104-a23f-704a074ef469'	System	02 Sep 2020 03:45:46
User entered 'No (N)'	System	02 Sep 2020 03:45:46

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:43', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '4b91adf3-bcbc-4104-a23f-704a074ef469'	System	02 Sep 2020 03:45:46
User entered '01 Sep 2020 22:45'	System	02 Sep 2020 03:45:46

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 7'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:10:04', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0714bf5d-d620-495c-b9c4-2b4318d71de2'	System	02 Sep 2020 18:11:16
User entered 'Yes (Y)'	System	02 Sep 2020 18:11:16

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0714bf5d-d620-495c-b9c4-2b4318d71de2'	System	02 Sep 2020 18:11:16
User entered '98.2'	System	02 Sep 2020 18:11:16

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0714bf5d-d620-495c-b9c4-2b4318d71de2'	System	02 Sep 2020 18:11:16
User entered 'No (N)'	System	02 Sep 2020 18:11:16

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0714bf5d-d620-495c-b9c4-2b4318d71de2'	System	02 Sep 2020 18:11:16
User entered '02 Sep 2020 13:11'	System	02 Sep 2020 18:11:16

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:28:49', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '62012e84-a596-435a-8247-4e7d4690b5bc'	System	27 Aug 2020 17:29:24
User entered 'None (1)'	System	27 Aug 2020 17:29:24

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:02', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '62012e84-a596-435a-8247-4e7d4690b5bc'	System	27 Aug 2020 17:29:24
User entered 'No (N)'	System	27 Aug 2020 17:29:24

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:07', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '62012e84-a596-435a-8247-4e7d4690b5bc'	System	27 Aug 2020 17:29:24
User entered 'No (N)'	System	27 Aug 2020 17:29:24

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '62012e84-a596-435a-8247-4e7d4690b5bc'	System	27 Aug 2020 17:29:24
User entered 'None (1)'	System	27 Aug 2020 17:29:24

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:19', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '62012e84-a596-435a-8247-4e7d4690b5bc'	System	27 Aug 2020 17:29:24
User entered '27 Aug 2020 12:29'	System	27 Aug 2020 17:29:24

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '27 Aug 2020 14:39'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:36:44', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7af6846b-a7e0-44f0-b6b3-4c82ee51e45f'	System	27 Aug 2020 21:38:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 21:38:25

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:37:07', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7af6846b-a7e0-44f0-b6b3-4c82ee51e45f'	System	27 Aug 2020 21:38:25
User entered 'No (N)'	System	27 Aug 2020 21:38:25

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7af6846b-a7e0-44f0-b6b3-4c82ee51e45f'	System	27 Aug 2020 21:38:25
User entered 'No (N)'	System	27 Aug 2020 21:38:25

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:15', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7af6846b-a7e0-44f0-b6b3-4c82ee51e45f'	System	27 Aug 2020 21:38:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 21:38:25

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:19', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7af6846b-a7e0-44f0-b6b3-4c82ee51e45f'	System	27 Aug 2020 21:38:25
User entered '27 Aug 2020 16:38'	System	27 Aug 2020 21:38:25

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '27 Aug 2020 15:34'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 2'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8d2b946b-5e87-44e3-b23f-38d479bd4fda'	System	28 Aug 2020 21:50:58
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 21:50:58

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:39', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8d2b946b-5e87-44e3-b23f-38d479bd4fda'	System	28 Aug 2020 21:50:58
User entered 'No (N)'	System	28 Aug 2020 21:50:58

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:46', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8d2b946b-5e87-44e3-b23f-38d479bd4fda'	System	28 Aug 2020 21:50:58
User entered 'No (N)'	System	28 Aug 2020 21:50:58

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8d2b946b-5e87-44e3-b23f-38d479bd4fda'	System	28 Aug 2020 21:50:58
User entered 'None (1)'	System	28 Aug 2020 21:50:58

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:53', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8d2b946b-5e87-44e3-b23f-38d479bd4fda'	System	28 Aug 2020 21:50:58
User entered '28 Aug 2020 16:50'	System	28 Aug 2020 21:50:58

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 3'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:25', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '17e8cd01-a0a9-48b5-a5a1-a576ef0f6c22'	System	29 Aug 2020 19:49:48
User entered 'None (1)'	System	29 Aug 2020 19:49:48

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:31', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '17e8cd01-a0a9-48b5-a5a1-a576ef0f6c22'	System	29 Aug 2020 19:49:48
User entered 'No (N)'	System	29 Aug 2020 19:49:48

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:33', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '17e8cd01-a0a9-48b5-a5a1-a576ef0f6c22'	System	29 Aug 2020 19:49:48
User entered 'No (N)'	System	29 Aug 2020 19:49:48

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:43', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '17e8cd01-a0a9-48b5-a5a1-a576ef0f6c22'	System	29 Aug 2020 19:49:48
User entered 'None (1)'	System	29 Aug 2020 19:49:48

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:46', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '17e8cd01-a0a9-48b5-a5a1-a576ef0f6c22'	System	29 Aug 2020 19:49:48
User entered '29 Aug 2020 14:49'	System	29 Aug 2020 19:49:48

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 4'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:45', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3469c646-2ab1-4418-b21f-8b39fe32ce22'	System	30 Aug 2020 23:47:56
User entered 'None (1)'	System	30 Aug 2020 23:47:56

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:47', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3469c646-2ab1-4418-b21f-8b39fe32ce22'	System	30 Aug 2020 23:47:56
User entered 'No (N)'	System	30 Aug 2020 23:47:56

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:48', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3469c646-2ab1-4418-b21f-8b39fe32ce22'	System	30 Aug 2020 23:47:56
User entered 'No (N)'	System	30 Aug 2020 23:47:56

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3469c646-2ab1-4418-b21f-8b39fe32ce22'	System	30 Aug 2020 23:47:56
User entered 'None (1)'	System	30 Aug 2020 23:47:56

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:53', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3469c646-2ab1-4418-b21f-8b39fe32ce22'	System	30 Aug 2020 23:47:56
User entered '30 Aug 2020 18:47'	System	30 Aug 2020 23:47:56

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 5'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '71d8c1af-6d27-49b5-bc89-2aace0abf415'	System	31 Aug 2020 17:20:45
User entered 'None (1)'	System	31 Aug 2020 17:20:45

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:05', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '71d8c1af-6d27-49b5-bc89-2aace0abf415'	System	31 Aug 2020 17:20:45
User entered 'No (N)'	System	31 Aug 2020 17:20:45

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:07', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '71d8c1af-6d27-49b5-bc89-2aace0abf415'	System	31 Aug 2020 17:20:45
User entered 'No (N)'	System	31 Aug 2020 17:20:45

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '71d8c1af-6d27-49b5-bc89-2aace0abf415'	System	31 Aug 2020 17:20:45
User entered 'None (1)'	System	31 Aug 2020 17:20:45

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '71d8c1af-6d27-49b5-bc89-2aace0abf415'	System	31 Aug 2020 17:20:45
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:20:45

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 6'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:47', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '25883b67-3097-4b4c-9419-c2ff1711d8cf'	System	02 Sep 2020 03:45:57
User entered 'None (1)'	System	02 Sep 2020 03:45:57

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:48', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '25883b67-3097-4b4c-9419-c2ff1711d8cf'	System	02 Sep 2020 03:45:57
User entered 'No (N)'	System	02 Sep 2020 03:45:57

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '25883b67-3097-4b4c-9419-c2ff1711d8cf'	System	02 Sep 2020 03:45:57
User entered 'No (N)'	System	02 Sep 2020 03:45:57

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:52', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '25883b67-3097-4b4c-9419-c2ff1711d8cf'	System	02 Sep 2020 03:45:57
User entered 'None (1)'	System	02 Sep 2020 03:45:57

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:54', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '25883b67-3097-4b4c-9419-c2ff1711d8cf'	System	02 Sep 2020 03:45:57
User entered '01 Sep 2020 22:45'	System	02 Sep 2020 03:45:57

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 7'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:18', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '26687e30-b776-4899-9767-3257d4efa02a'	System	02 Sep 2020 18:11:28
User entered 'None (1)'	System	02 Sep 2020 18:11:28

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:19', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '26687e30-b776-4899-9767-3257d4efa02a'	System	02 Sep 2020 18:11:28
User entered 'No (N)'	System	02 Sep 2020 18:11:28

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:21', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '26687e30-b776-4899-9767-3257d4efa02a'	System	02 Sep 2020 18:11:28
User entered 'No (N)'	System	02 Sep 2020 18:11:28

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:23', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '26687e30-b776-4899-9767-3257d4efa02a'	System	02 Sep 2020 18:11:28
User entered 'None (1)'	System	02 Sep 2020 18:11:28

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:26', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '26687e30-b776-4899-9767-3257d4efa02a'	System	02 Sep 2020 18:11:28
User entered '02 Sep 2020 13:11'	System	02 Sep 2020 18:11:28

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:22', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'None (0)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:27', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:30', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'None (0)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'None (0)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:44', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:49', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered 'No (N)'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T12:29:51', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6989bbf9-4931-415a-85cb-52df95cf1069'	System	27 Aug 2020 17:29:54
User entered '27 Aug 2020 12:29'	System	27 Aug 2020 17:29:54

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '27 Aug 2020 14:39'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:23', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'None (0)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:26', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'No interference with activity (1)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:29', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'No interference with activity (1)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:32', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'No interference with activity (1)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'None (0)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'None (0)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:41', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered 'No (N)'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-27T16:38:43', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '69be26ff-c433-459b-b978-33a280cc749c'	System	27 Aug 2020 21:38:45
User entered '27 Aug 2020 16:38'	System	27 Aug 2020 21:38:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '27 Aug 2020 15:34'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 2'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:50:57', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'None (0)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'No interference with activity (1)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'No interference with activity (1)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:06', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'No interference with activity (1)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'None (0)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'None (0)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered 'No (N)'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-28T16:51:18', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'bea9d254-ba48-4fa5-800f-e4eaf2cd9d2e'	System	28 Aug 2020 21:51:21
User entered '28 Aug 2020 16:51'	System	28 Aug 2020 21:51:21

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 3'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:49', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'None (0)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:53', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'None (0)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:49:58', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:01', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'None (0)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:06', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'None (0)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered 'No (N)'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-29T14:50:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0817a7ec-cf5b-4b6e-acab-607ac2b1e96c'	System	29 Aug 2020 19:50:14
User entered '29 Aug 2020 14:50'	System	29 Aug 2020 19:50:14

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 4'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:56', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'None (0)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:47:58', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'None (0)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:01', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'None (0)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:04', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'None (0)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:06', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'None (0)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'None (0)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered 'No (N)'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-30T18:48:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'f5c29a4a-91e6-421b-8afa-ea12ccb83adb'	System	30 Aug 2020 23:48:13
User entered '30 Aug 2020 18:48'	System	30 Aug 2020 23:48:13

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 5'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'None (0)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:25', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'None (0)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:27', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'None (0)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:32', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'None (0)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'None (0)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:35', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'None (0)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered 'No (N)'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-08-31T12:13:42', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3d08647a-94f5-4a78-80fe-2ef0cd0e6db4'	System	31 Aug 2020 17:23:45
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:23:45

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 6'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:57', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'None (0)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:45:59', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'None (0)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:46:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'None (0)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:46:04', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'None (0)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:46:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'None (0)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:46:14', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'None (0)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:46:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered 'No (N)'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-01T22:46:20', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c8b63c00-95cc-4338-84a5-429761c4cdee'	System	02 Sep 2020 03:46:25
User entered '01 Sep 2020 22:46'	System	02 Sep 2020 03:46:25

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 7'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:29', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'None (0)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:30', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'None (0)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:31', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'None (0)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:32', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'None (0)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'None (0)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:35', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'None (0)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered 'No (N)'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-02T13:11:39', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '590c0fb6-df31-4e13-bccd-a4f0fbc55c4a'	System	02 Sep 2020 18:11:41
User entered '02 Sep 2020 13:11'	System	02 Sep 2020 18:11:41

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 17:26:09

US3572116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:03
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:31:59

US3572116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '3 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:31:59

US3572116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:31:59

US3572116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:31:59

US3572116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 17:54:08

US3572116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	10 Sep 2020 17:54:08

US3572116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 18:05:27

US3572116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '10 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 18:05:27

US3572116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Jasmine Ali (b) (4)	10 Sep 2020 20:42:39
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	Jasmine Ali (b) (4)	10 Sep 2020 18:05:27
	(b) (4)	

US3572116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'vm @ 1:04P'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 18:05:27

US3572116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 20:42:45

US3572116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	10 Sep 2020 20:42:45

US3572116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:32:23

US3572116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '17 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:32:23

US3572116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:32:23

US3572116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:32:23

US3572116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:32:29

US3572116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	17 Sep 2020 20:32:29

US3572116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:33:24

US3572116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:33:24

US3572116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Clinic (Clinic)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:33:24

US3572116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'VISIT2'	System	15 Oct 2020 20:33:24

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Pre-Dose (PREDOSE)'	Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '10:19'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '25 Sep 2020 10:19'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '98.1' F	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Other (Other)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Temporal'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '69'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'bpm'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '18'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'breaths/min'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '121'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '71'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Post-Dose (POSTDOSE)'	Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '11:16'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '25 Sep 2020 11:16'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '97.7' F	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Other (Other)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Temporal'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '60'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'bpm'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '18'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'breaths/min'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '108'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (u) (4), (b) (6)	09 Dec 2020 14:08:37
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Alisha Lutat (b) (4) (b) (4)	09 Dec 2020 01:30:33
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Oct 2020 20:36:04
User entered '57'	Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	15 Oct 2020 20:36:04

US3572116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:01

US3572116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:38:01

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Urine (URINE)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Negative (NEGATIVE)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered empty.	System	15 Oct 2020 20:38:42

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '10:46'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '25 Sep 2020 10:46'	System	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'ONCE'	System	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 15:53:36

US3572116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:39:07

US3572116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:39:07

US3572116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '10:21'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:39:07

US3572116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '25 Sep 2020 10:21'	System	15 Oct 2020 20:39:07

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '25 Sep 2020'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '10:15'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '25 Sep 2020 10:15'	System	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'No (N)'	(b) (4) Brett Potthoff (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered empty.	System	15 Oct 2020 20:39:26

US3572116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 16:05:07

US3572116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'I'	System	02 Oct 2020 16:05:07

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:13:35', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd585e8da-74d4-4d2a-af97-e0a2e99711d6'	System	25 Sep 2020 16:13:48
User entered 'Yes (Y)'	System	25 Sep 2020 16:13:48

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:13:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd585e8da-74d4-4d2a-af97-e0a2e99711d6' User entered '97.7'	System	25 Sep 2020 16:13:48
	System	25 Sep 2020 16:13:48

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:13:42', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd585e8da-74d4-4d2a-af97-e0a2e99711d6'	System	25 Sep 2020 16:13:48
User entered 'No (N)'	System	25 Sep 2020 16:13:48

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:13:45', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd585e8da-74d4-4d2a-af97-e0a2e99711d6'	System	25 Sep 2020 16:13:48
User entered '25 Sep 2020 11:13'	System	25 Sep 2020 16:13:48

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 11:06'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 13:36'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:51:28', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7c21b56d-1176-4e47-a409-9f3dc2eb630d'	System	26 Sep 2020 05:52:42
User entered 'Yes (Y)'	System	26 Sep 2020 05:52:42

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:52:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7c21b56d-1176-4e47-a409-9f3dc2eb630d' User entered '98.9'	System	26 Sep 2020 05:52:42

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:52:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7c21b56d-1176-4e47-a409-9f3dc2eb630d'	System	26 Sep 2020 05:52:42
User entered 'No (N)'	System	26 Sep 2020 05:52:42

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:52:39', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7c21b56d-1176-4e47-a409-9f3dc2eb630d'	System	26 Sep 2020 05:52:42
User entered '26 Sep 2020 00:52'	System	26 Sep 2020 05:52:42

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 14:31'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 2'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:38:06', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3c30a2d-d5f6-412b-b290-d4e8968527ad'	System	26 Sep 2020 22:38:24
User entered 'Yes (Y)'	System	26 Sep 2020 22:38:24

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:38:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3c30a2d-d5f6-412b-b290-d4e8968527ad' User entered '98.8'	System	26 Sep 2020 22:38:24
	System	26 Sep 2020 22:38:24

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:38:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3c30a2d-d5f6-412b-b290-d4e8968527ad'	System	26 Sep 2020 22:38:24
User entered 'Yes (Y)'	System	26 Sep 2020 22:38:24

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ibuprofen 200mg pain' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 07:20:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ibuprofen 200mg pain' (Site from System).	Jessica McDowell (b) (4)	02 Oct 2020 16:42:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:38:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3c30a2d-d5f6-412b-b290-d4e8968527ad'	System	26 Sep 2020 22:38:24
User entered '1'	System	26 Sep 2020 22:38:24

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:38:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3c30a2d-d5f6-412b-b290-d4e8968527ad' User entered '0'	System	26 Sep 2020 22:38:24
	System	26 Sep 2020 22:38:24

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:38:20', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b3c30a2d-d5f6-412b-b290-d4e8968527ad'	System	26 Sep 2020 22:38:24
User entered '26 Sep 2020 17:38'	System	26 Sep 2020 22:38:24

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 3'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 4'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:24', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e339b891-ca5f-4f76-b45b-e9f261df38a7'	System	28 Sep 2020 22:39:44
User entered 'Yes (Y)'	System	28 Sep 2020 22:39:44

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:28', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e339b891-ca5f-4f76-b45b-e9f261df38a7'	System	28 Sep 2020 22:39:44
User entered '98.8'	System	28 Sep 2020 22:39:44

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:35', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e339b891-ca5f-4f76-b45b-e9f261df38a7'	System	28 Sep 2020 22:39:44
User entered 'Yes (Y)'	System	28 Sep 2020 22:39:44

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ibuprofen' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 07:19:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:39', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e339b891-ea5f-4f76-b45b-e9f261df38a7'	Jessica McDowell (b) (4)	02 Oct 2020 16:42:45
User entered '1'	System	28 Sep 2020 22:39:44
	System	28 Sep 2020 22:39:44
	System	28 Sep 2020 22:39:44

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:39', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e339b891-ca5f-4f76-b45b-e9f261df38a7'	System	28 Sep 2020 22:39:44
User entered '0'	System	28 Sep 2020 22:39:44

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:41', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e339b891-ca5f-4f76-b45b-e9f261df38a7'	System	28 Sep 2020 22:39:44
User entered '28 Sep 2020 17:39'	System	28 Sep 2020 22:39:44

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 5'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:20', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd9660085-9deb-46f3-8f18-bb283ca1060b'	System	30 Sep 2020 04:18:35
User entered 'Yes (Y)'	System	30 Sep 2020 04:18:35

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:26', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd9660085-9deb-46f3-8f18-bb283ca1060b' User entered '98.9'	System	30 Sep 2020 04:18:35
	System	30 Sep 2020 04:18:35

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:28', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd9660085-9deb-46f3-8f18-bb283ca1060b'	System	30 Sep 2020 04:18:35
User entered 'No (N)'	System	30 Sep 2020 04:18:35

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:31', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'd9660085-9deb-46f3-8f18-bb283ca1060b'	System	30 Sep 2020 04:18:35
User entered '29 Sep 2020 23:18'	System	30 Sep 2020 04:18:35

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 6'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:40', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6013cbbe-1660-4147-a768-8bb3df720f66'	System	01 Oct 2020 05:09:55
User entered 'Yes (Y)'	System	01 Oct 2020 05:09:55

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:44', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6013cbbe-1660-4147-a768-8bb3df720f66'	System	01 Oct 2020 05:09:55
User entered '98.6'	System	01 Oct 2020 05:09:55

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:48', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6013cbbe-1660-4147-a768-8bb3df720f66'	System	01 Oct 2020 05:09:55
User entered 'No (N)'	System	01 Oct 2020 05:09:55

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6013cbbe-1660-4147-a768-8bb3df720f66'	System	01 Oct 2020 05:09:55
User entered '01 Oct 2020 00:09'	System	01 Oct 2020 05:09:55

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 7'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:13:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e9cba7c2-ef72-44ad-987a-48c326fbe57b'	System	25 Sep 2020 16:14:11
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 16:14:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:13:55', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e9cba7c2-ef72-44ad-987a-48c326fbe57b'	System	25 Sep 2020 16:14:11
User entered 'No (N)'	System	25 Sep 2020 16:14:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e9cba7c2-ef72-44ad-987a-48c326fbe57b'	System	25 Sep 2020 16:14:11
User entered 'No (N)'	System	25 Sep 2020 16:14:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e9cba7c2-ef72-44ad-987a-48c326fbe57b'	System	25 Sep 2020 16:14:11
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 16:14:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:05', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e9cba7c2-ef72-44ad-987a-48c326fbe57b'	System	25 Sep 2020 16:14:11
User entered '25 Sep 2020 11:14'	System	25 Sep 2020 16:14:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 11:06'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 13:36'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fe71d64a-9ddd-4420-b82f-27d4c2138b76'	System	26 Sep 2020 05:53:28
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 05:53:28

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:06', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fe71d64a-9ddd-4420-b82f-27d4c2138b76'	System	26 Sep 2020 05:53:28
User entered 'No (N)'	System	26 Sep 2020 05:53:28

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:15', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fe71d64a-9ddd-4420-b82f-27d4c2138b76'	System	26 Sep 2020 05:53:28
User entered 'No (N)'	System	26 Sep 2020 05:53:28

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:21', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fe71d64a-9ddd-4420-b82f-27d4c2138b76'	System	26 Sep 2020 05:53:28
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 05:53:28

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:24', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'fe71d64a-9ddd-4420-b82f-27d4c2138b76'	System	26 Sep 2020 05:53:28
User entered '26 Sep 2020 00:53'	System	26 Sep 2020 05:53:28

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 14:31'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 2'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:35:28', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:35:29', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered 'Yes (Y)'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:36:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered '30'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:36:18', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered 'Yes (Y)'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:02', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered '30'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:06', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5d0bdf7d-ac57-4a94-9828-1f4db0a42fbe'	System	26 Sep 2020 22:37:11
User entered '26 Sep 2020 17:37'	System	26 Sep 2020 22:37:11

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 3'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 4'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:39:52', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3ef995d8-7a82-4610-a896-e15248c17fb8'	System	28 Sep 2020 22:40:41
User entered 'None (1)'	System	28 Sep 2020 22:40:41

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:40:27', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3ef995d8-7a82-4610-a896-e15248c17fb8'	System	28 Sep 2020 22:40:41
User entered 'No (N)'	System	28 Sep 2020 22:40:41

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:40:29', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3ef995d8-7a82-4610-a896-e15248c17fb8'	System	28 Sep 2020 22:40:41
User entered 'No (N)'	System	28 Sep 2020 22:40:41

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:40:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3ef995d8-7a82-4610-a896-e15248c17fb8'	System	28 Sep 2020 22:40:41
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 22:40:41

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:40:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3ef995d8-7a82-4610-a896-e15248c17fb8'	System	28 Sep 2020 22:40:41
User entered '28 Sep 2020 17:40'	System	28 Sep 2020 22:40:41

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 5'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5a13bce8-ac88-4101-8266-2a4d57b1751d'	System	30 Sep 2020 04:18:51
User entered 'None (1)'	System	30 Sep 2020 04:18:51

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5a13bce8-ac88-4101-8266-2a4d57b1751d'	System	30 Sep 2020 04:18:51
User entered 'No (N)'	System	30 Sep 2020 04:18:51

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:40', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5a13bce8-ac88-4101-8266-2a4d57b1751d'	System	30 Sep 2020 04:18:51
User entered 'No (N)'	System	30 Sep 2020 04:18:51

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:45', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5a13bce8-ac88-4101-8266-2a4d57b1751d'	System	30 Sep 2020 04:18:51
User entered 'None (1)'	System	30 Sep 2020 04:18:51

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:48', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '5a13bce8-ac88-4101-8266-2a4d57b1751d'	System	30 Sep 2020 04:18:51
User entered '29 Sep 2020 23:18'	System	30 Sep 2020 04:18:51

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 6'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:54', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2d49549c-8bfb-40f2-b303-d85d77810f71'	System	01 Oct 2020 05:10:07
User entered 'None (1)'	System	01 Oct 2020 05:10:07

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:56', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2d49549c-8bf2-b303-d85d77810f71'	System	01 Oct 2020 05:10:07
User entered 'No (N)'	System	01 Oct 2020 05:10:07

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:09:58', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2d49549c-8bfb-40f2-b303-d85d77810f71'	System	01 Oct 2020 05:10:07
User entered 'No (N)'	System	01 Oct 2020 05:10:07

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2d49549c-8bfb-40f2-b303-d85d77810f71'	System	01 Oct 2020 05:10:07
User entered 'None (1)'	System	01 Oct 2020 05:10:07

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:02', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2d49549c-8bf2-b303-d85d77810f71'	System	01 Oct 2020 05:10:07
User entered '01 Oct 2020 00:10'	System	01 Oct 2020 05:10:07

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 7'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:08', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'None (0)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'None (0)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'None (0)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'None (0)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'None (0)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:14', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'None (0)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered 'No (N)'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-25T11:14:18', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'abb33c91-2711-4a1b-829c-dd82fa502d05'	System	25 Sep 2020 16:14:20
User entered '25 Sep 2020 11:14'	System	25 Sep 2020 16:14:20

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 11:06'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 13:36'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:33', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'No interference with activity (1)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'Some interference with activity (2)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:40', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'Some interference with activity (2)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:43', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'Some interference with activity (2)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:49', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:52', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'None (0)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:55', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered 'No (N)'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T00:53:59', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '389aff68-cced-4a42-bba7-7ae7014e1be8'	System	26 Sep 2020 05:54:01
User entered '26 Sep 2020 00:53'	System	26 Sep 2020 05:54:01

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '25 Sep 2020 14:31'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 2'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'None (0)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:15', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'None (0)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:17', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'Some interference with activity (2)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:48', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'Some interference with activity (2)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'None (0)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:54', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:56', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered 'No (N)'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-26T17:37:59', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'a645ceef-4bf5-4e02-a5b0-6f524641f2b7'	System	26 Sep 2020 22:38:02
User entered '26 Sep 2020 17:37'	System	26 Sep 2020 22:38:02

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 3'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 4'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:40:41', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'None (0)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:40:58', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'No interference with activity (1)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:41:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'No interference with activity (1)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:41:05', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'No interference with activity (1)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:41:07', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'None (0)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:41:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'None (0)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:41:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered 'No (N)'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-28T17:41:12', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'daca2a70-1941-4518-b8ec-7cc989bba2ae'	System	28 Sep 2020 22:41:15
User entered '28 Sep 2020 17:41'	System	28 Sep 2020 22:41:15

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 5'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:52', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:18:56', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'Some interference with activity (2)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:19:04', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:19:02', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:19:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'None (0)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:19:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'None (0)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:19:14', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered 'No (N)'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-09-29T23:19:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e451c2ea-f735-4bfe-9e16-58389834d273'	System	30 Sep 2020 04:19:16
User entered '29 Sep 2020 23:19'	System	30 Sep 2020 04:19:16

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 6'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'No interference with activity (1)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'None (0)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'No interference with activity (1)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:15', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'None (0)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'None (0)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:18', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'None (0)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:19', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered 'No (N)'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-10-01T00:10:21', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cc93ad-6f6f-47c5-8925-e3d50aed421a'	System	01 Oct 2020 05:10:24
User entered '01 Oct 2020 00:10'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	25 Sep 2020 15:53:36
User entered 'Day 7'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:53:36

US3572116

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	01 Oct 2020 05:10:24
User entered 'Day 8'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:19:24

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	01 Oct 2020 05:10:24
User entered 'Day 8'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:19:24

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	01 Oct 2020 05:10:24
User entered 'Day 8'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06

US3572116

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 05:10:24

US3572116

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:19:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 05:10:24

US3572116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 16:05:18

US3572116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '2 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 16:05:18

US3572116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 16:05:18

US3572116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 16:05:18

US3572116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	02 Oct 2020 16:05:22

US3572116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	02 Oct 2020 16:05:22

US3572116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	09 Oct 2020 22:29:16

US3572116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '9 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	09 Oct 2020 22:29:16

US3572116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	09 Oct 2020 22:29:16

US3572116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	09 Oct 2020 22:29:16

US3572116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	09 Oct 2020 22:29:33

US3572116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	09 Oct 2020 22:29:33

US3572116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:40:55
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'EDC immunogenicity assessment is updated accordingly for Visit 3 Day 57 per source' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 19:56:54
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:59:44
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	16 Oct 2020 19:23:17

US3572116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '16 Oct 2020'	(b) (4) Jessica McDowell (b) (4)	16 Oct 2020 19:23:17

US3572116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	16 Oct 2020 19:23:17

US3572116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	16 Oct 2020 19:23:17

US3572116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	16 Oct 2020 19:23:23

US3572116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	16 Oct 2020 19:23:23

US3572116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:04:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Oct 2020'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:04:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:04:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'VISIT3'	System	26 Feb 2021 21:04:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '08:42'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Oct 2020 08:42'	System	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'temporal'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '72'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'bpm'	System	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '18'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'breaths/min'	System	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '107'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '65'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'mmHg'	System	26 Feb 2021 21:05:50

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24

US3572116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24

US3572116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:16

US3572116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Oct 2020'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:06:16

US3572116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 19:56:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '27 Oct 2020'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 19:56:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered '08:58'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 19:56:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered '27 Oct 2020 08:58'	System	05 Feb 2021 19:56:28

US3572116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:11:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	17 Nov 2020 19:36:51

US3572116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'I'	System	17 Nov 2020 19:36:51

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 64'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Please 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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Please 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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Please 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)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00
Data entry locked.	System	27 Aug 2020 17:26:09
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:02:00
Data entry locked.	System	27 Aug 2020 17:26:09
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 71'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-06T00:13:56', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2aa6d8c6-3a3b-46a2-a7a4-944393b06b34'	System	06 Nov 2020 06:14:08
User entered 'No (N)'	System	06 Nov 2020 06:14:08

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-06T00:13:59', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2aa6d8c6-3a3b-46a2-a7a4-944393b06b34'	System	06 Nov 2020 06:14:08
User entered 'No (N)'	System	06 Nov 2020 06:14:08

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-06T00:14:03', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '2aa6d8c6-3a3b-46a2-a7a4-944393b06b34'	System	06 Nov 2020 06:14:08
User entered '06 Nov 2020 00:14:03'	System	06 Nov 2020 06:14:08

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered 'Day 78'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-10T00:06:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c16d95a5-a1c3-4e59-a774-ad097e24eee2'	System	10 Nov 2020 06:06:19
User entered 'No (N)'	System	10 Nov 2020 06:06:19

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-10T00:06:14', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c16d95a5-a1c3-4e59-a774-ad097e24eee2'	System	10 Nov 2020 06:06:19
User entered 'No (N)'	System	10 Nov 2020 06:06:19

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-10T00:06:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c16d95a5-a1c3-4e59-a774-ad097e24eee2'	System	10 Nov 2020 06:06:19
User entered '10 Nov 2020 00:06:16'	System	10 Nov 2020 06:06:19

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 17:26:09

US3572116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:17:06
Data entry locked.	System	27 Aug 2020 17:26:09
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 17:26:09

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2020-11-21T00:01:40', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7732ee43-d1e2-479b-9245-153657eafc41'	System	21 Nov 2020 06:02:23
User entered 'No (N)'	System	21 Nov 2020 06:02:23

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2020-11-21T00:01:42', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7732ee43-d1e2-479b-9245-153657eafc41'	System	21 Nov 2020 06:02:23
User entered 'Yes (Y)'	System	21 Nov 2020 06:02:23

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Please 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 (77f2560d810627e2)', Time: '2020-11-21T00:01:47', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7732ee43-d1e2-479b-9245-153657eafc41'	System	21 Nov 2020 06:02:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 06:02:23

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-21T00:01:53', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7732ee43-d1e2-479b-9245-153657eafc41'	System	21 Nov 2020 06:02:23
User entered '21 Nov 2020 00:01:53'	System	21 Nov 2020 06:02:23

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2020-11-28T00:01:14', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c3b4c60d-c827-4e26-969d-f82ffdb79940'	System	28 Nov 2020 06:02:19
User entered 'No (N)'	System	28 Nov 2020 06:02:19

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2020-11-28T00:01:29', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c3b4c60d-c827-4e26-969d-f82ffdb79940'	System	28 Nov 2020 06:02:19
User entered 'No (N)'	System	28 Nov 2020 06:02:19

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-11-28T00:01:32', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'c3b4c60d-c827-4e26-969d-f82ffdb79940'	System	28 Nov 2020 06:02:19
User entered '28 Nov 2020 00:01:32'	System	28 Nov 2020 06:02:19

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2020-12-05T01:27:33', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8b152bae-f0af-495e-9f4a-cfb63f71b025'	System	05 Dec 2020 07:27:37
User entered 'No (N)'	System	05 Dec 2020 07:27:37

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2020-12-05T01:27:21', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8b152bae-f0af-495e-9f4a-cfb63f71b025'	System	05 Dec 2020 07:27:37
User entered 'No (N)'	System	05 Dec 2020 07:27:37

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-12-05T01:27:35', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '8b152bae-f0af-495e-9f4a-cfb63f71b025'	System	05 Dec 2020 07:27:37
User entered '05 Dec 2020 01:27:35'	System	05 Dec 2020 07:27:37

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2020-12-12T03:10:07', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '931bb700-24a1-4d58-ad93-1af03ccd7cf0'	System	12 Dec 2020 11:10:19
User entered 'No (N)'	System	12 Dec 2020 11:10:19

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2020-12-12T03:10:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '931bb700-24a1-4d58-ad93-1af03ccd7cf0'	System	12 Dec 2020 11:10:19
User entered 'No (N)'	System	12 Dec 2020 11:10:19

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-12-12T03:10:13', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '931bb700-24a1-4d58-ad93-1af03ccd7cf0'	System	12 Dec 2020 11:10:19
User entered '12 Dec 2020 03:10:13'	System	12 Dec 2020 11:10:19

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2020-12-29T14:52:53', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0af189e2-3ba8-41ae-95a1-0cac26d82739'	System	29 Dec 2020 22:53:03
User entered 'No (N)'	System	29 Dec 2020 22:53:03

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2020-12-29T14:52:55', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0af189e2-3ba8-41ae-95a1-0cac26d82739'	System	29 Dec 2020 22:53:03
User entered 'No (N)'	System	29 Dec 2020 22:53:03

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2020-12-29T14:52:57', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '0af189e2-3ba8-41ae-95a1-0cac26d82739'	System	29 Dec 2020 22:53:03
User entered '29 Dec 2020 14:52:57'	System	29 Dec 2020 22:53:03

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-01-02T13:08:49', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e09a410e-ee6f-4b4f-a93c-31dc2dcc4953'	System	02 Jan 2021 21:08:59
User entered 'No (N)'	System	02 Jan 2021 21:08:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-01-02T13:08:52', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e09a410e-ee6f-4b4f-a93c-31dc2dcc4953'	System	02 Jan 2021 21:08:59
User entered 'No (N)'	System	02 Jan 2021 21:08:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-02T13:08:54', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e09a410e-ee6f-4b4f-a93c-31dc2dcc4953'	System	02 Jan 2021 21:08:59
User entered '02 Jan 2021 13:08:54'	System	02 Jan 2021 21:08:59

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-01-10T01:27:10', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'Yes (Y)'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-01-10T01:27:16', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'No (N)'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-01-10T01:27:20', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'Yes (Y)'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'l'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'l'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered 'l'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered '0'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Please 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 (77f2560d810627e2)', Time: '2021-01-10T01:27:42', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-01-10T01:27:46', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2'	System	10 Jan 2021 09:28:01
User entered 'No (N)'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-10T01:27:50', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'e778fa96-bee3-4d8d-b4e9-d6e2754f7dd2' User entered '10 Jan 2021 01:27:50'	System	10 Jan 2021 09:28:01

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-01-20T09:24:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '962257a2-f5cd-4a10-bc16-1e9125ff2620'	System	20 Jan 2021 15:24:44
User entered 'No (N)'	System	20 Jan 2021 15:24:44

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-01-20T09:24:39', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '962257a2-f5cd-4a10-bc16-1e9125ff2620'	System	20 Jan 2021 15:24:44
User entered 'No (N)'	System	20 Jan 2021 15:24:44

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-20T09:24:42', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '962257a2-f5cd-4a10-bc16-1e9125ff2620' User entered '20 Jan 2021 09:24:42'	System	20 Jan 2021 15:24:44
	System	20 Jan 2021 15:24:44

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-01-30T13:59:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'dbea1e92-5169-472f-aea5-124a0abcb053'	System	30 Jan 2021 19:59:16
User entered 'No (N)'	System	30 Jan 2021 19:59:16

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-01-30T13:59:11', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'dbea1e92-5169-472f-aea5-124a0abcb053'	System	30 Jan 2021 19:59:16
User entered 'No (N)'	System	30 Jan 2021 19:59:16

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-01-30T13:59:14', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'dbea1e92-5169-472f-aea5-124a0abcb053'	System	30 Jan 2021 19:59:16
User entered '30 Jan 2021 13:59:14'	System	30 Jan 2021 19:59:16

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-02-08T10:50:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3506f753-a767-4765-ac72-61fa3d6d9919'	System	08 Feb 2021 16:50:42
User entered 'No (N)'	System	08 Feb 2021 16:50:42

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-02-08T10:50:37', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3506f753-a767-4765-ac72-61fa3d6d9919'	System	08 Feb 2021 16:50:42
User entered 'No (N)'	System	08 Feb 2021 16:50:42

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-02-08T10:50:38', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '3506f753-a767-4765-ac72-61fa3d6d9919' User entered '08 Feb 2021 10:50:38'	System	08 Feb 2021 16:50:42
	System	08 Feb 2021 16:50:42

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-02-15T19:47:05', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b2777809-0c75-48b2-8bb5-8bfca7733380'	System	16 Feb 2021 01:47:11
User entered 'No (N)'	System	16 Feb 2021 01:47:11

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-02-15T19:47:07', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b2777809-0c75-48b2-8bb5-8bfca7733380'	System	16 Feb 2021 01:47:11
User entered 'No (N)'	System	16 Feb 2021 01:47:11

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-02-15T19:47:09', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: 'b2777809-0c75-48b2-8bb5-8bfca7733380'	System	16 Feb 2021 01:47:11
User entered '15 Feb 2021 19:47:09'	System	16 Feb 2021 01:47:11

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-02-20T00:01:34', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '28a56c82-a98a-4573-9286-44357e5ae96d'	System	20 Feb 2021 06:02:32
User entered 'No (N)'	System	20 Feb 2021 06:02:32

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-02-20T00:01:36', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '28a56c82-a98a-4573-9286-44357e5ae96d'	System	20 Feb 2021 06:02:32
User entered 'No (N)'	System	20 Feb 2021 06:02:32

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-02-20T00:01:43', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '28a56c82-a98a-4573-9286-44357e5ae96d' User entered '20 Feb 2021 00:01:43'	System	20 Feb 2021 06:02:32

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-03-03T18:24:18-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7563263d-d81a-473f-86ac-93fa3c11489e'	System	04 Mar 2021 00:24:25
User entered 'No (N)'	System	04 Mar 2021 00:24:25

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-03-03T18:24:20-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7563263d-d81a-473f-86ac-93fa3c11489e'	System	04 Mar 2021 00:24:25
User entered 'No (N)'	System	04 Mar 2021 00:24:25

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-03-03T18:24:22-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7563263d-d81a-473f-86ac-93fa3c11489e' User entered '03 Mar 2021 18:24:22'	System	04 Mar 2021 00:24:25
	System	04 Mar 2021 00:24:25

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-03-13T11:23:13-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7f01ea23-4361-40e3-b4b5-b2a3d901a182'	System	13 Mar 2021 17:23:20
User entered 'No (N)'	System	13 Mar 2021 17:23:20

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-03-13T11:23:14-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7f01ea23-4361-40e3-b4b5-b2a3d901a182'	System	13 Mar 2021 17:23:20
User entered 'No (N)'	System	13 Mar 2021 17:23:20

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-03-13T11:23:17-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '7f01ea23-4361-40e3-b4b5-b2a3d901a182'	System	13 Mar 2021 17:23:20
User entered '13 Mar 2021 11:23:17'	System	13 Mar 2021 17:23:20

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-03-31T11:27:57-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '820c8dab-d7ee-4b6c-8cf7-fea71f2d1cac'	System	31 Mar 2021 16:28:06
User entered 'No (N)'	System	31 Mar 2021 16:28:06

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-03-31T11:27:59-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '820c8dab-d7ee-4b6c-8cf7-fea71f2d1cac'	System	31 Mar 2021 16:28:06
User entered 'No (N)'	System	31 Mar 2021 16:28:06

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-03-31T11:28:00-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '820c8dab-d7ee-4b6c-8cf7-fea71f2d1cac' User entered '31 Mar 2021 11:28:00'	System	31 Mar 2021 16:28:06
	System	31 Mar 2021 16:28:06

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-04-03T00:02:06-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cf3208-569f-4ead-ab48-b31ee9597bcf' User entered 'No (N)'	System	03 Apr 2021 05:20:07
	System	03 Apr 2021 05:20:07

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-04-03T00:02:08-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cf3208-569f-4ead-ab48-b31ee9597bcf' User entered 'No (N)'	System	03 Apr 2021 05:20:07

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-04-03T00:02:11-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '36cf3208-569f-4ead-ab48-b31ee9597bcf' User entered '03 Apr 2021 00:02:11'	System	03 Apr 2021 05:20:07
	System	03 Apr 2021 05:20:07

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[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 (77f2560d810627e2)', Time: '2021-04-26T12:40:16-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6c315ffc-37f2-497b-8980-60fb78e0e824'	System	26 Apr 2021 17:40:21
User entered 'No (N)'	System	26 Apr 2021 17:40:21

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

Have you been exposed to someone with 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 (77f2560d810627e2)', Time: '2021-04-26T12:40:19-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6c315ffc-37f2-497b-8980-60fb78e0e824'	System	26 Apr 2021 17:40:21
User entered 'No (N)'	System	26 Apr 2021 17:40:21

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-04-26T12:40:21-05:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '6c315ffc-37f2-497b-8980-60fb78e0e824'	System	26 Apr 2021 17:40:21
User entered '26 Apr 2021 12:40:21'	System	26 Apr 2021 17:40:21

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:02:00

US3572116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:02:00
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:02:00

US3572116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:19:24

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)	24 Apr 2021 16:32:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-03-03T18:24:11-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '01188203-721c-4536-8c9b-acc0985b615c'	System	04 Mar 2021 00:24:20
User entered 'No (N)'	System	04 Mar 2021 00:24:20

US3572116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:19:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77f2560d810627e2)', Time: '2021-03-03T18:24:13-06:00', User OID: 'PatientReportedOutcome (US3572116)', ODM File OID: '01188203-721c-4536-8c9b-acc0985b615c' User entered '03 Mar 2021 18:24:13'	System	04 Mar 2021 00:24:20
	System	04 Mar 2021 00:24:20

US3572116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:28
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	17 Nov 2020 19:37:01

US3572116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:28
User entered '17 Nov 2020'	(b) (4) Jessica McDowell (b) (4)	17 Nov 2020 19:37:01

US3572116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	17 Nov 2020 19:37:01

US3572116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:28
User entered empty.	(b) (4) Jessica McDowell (b) (4)	17 Nov 2020 19:37:01

US3572116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:28
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	17 Nov 2020 19:37:06

US3572116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:24
User entered 'l'	System	17 Nov 2020 19:37:06

US3572116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	29 Dec 2020 22:51:55

US3572116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '29 Dec 2020'	(b) (4) Jessica McDowell (b) (4)	29 Dec 2020 22:51:55

US3572116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	29 Dec 2020 22:51:55

US3572116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jessica McDowell (b) (4)	29 Dec 2020 22:51:55

US3572116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	29 Dec 2020 22:52:00

US3572116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User entered 'l'	System	29 Dec 2020 22:52:00

US3572116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	20 Jan 2021 17:18:30

US3572116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '20 Jan 2021'	(b) (4) Jessica McDowell (b) (4)	20 Jan 2021 17:18:30

US3572116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	20 Jan 2021 17:18:30

US3572116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jessica McDowell (b) (4)	20 Jan 2021 17:18:30

US3572116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	20 Jan 2021 17:18:34

US3572116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User entered 'l'	System	20 Jan 2021 17:18:34

US3572116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	20 Feb 2021 00:15:21

US3572116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '19 Feb 2021'	(b) (4) Jessica McDowell (b) (4)	20 Feb 2021 00:15:21

US3572116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	20 Feb 2021 00:15:21

US3572116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jessica McDowell (b) (4)	20 Feb 2021 00:15:21

US3572116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	20 Feb 2021 00:15:10

US3572116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:45
User entered 'l'	System	20 Feb 2021 00:15:10

US3572116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:48:35

US3572116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 19:48:35

US3572116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:48:44

US3572116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '26 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:48:44

US3572116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:48:44

US3572116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:48:44

US3572116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:48:48

US3572116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 19:48:48

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '3 Sep 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	03 Sep 2020 22:03:37

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '18:00'	(b) (4) Jessica McDowell (b) (4)	03 Sep 2020 22:03:37
	(b) (4)	

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:03
User entered '3 Sep 2020 18:00'	System	03 Sep 2020 22:03:37

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Safety Call (Safety Call)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	03 Sep 2020 22:03:37

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	03 Sep 2020 22:03:37
	(b) (4)	

US3572116

Folder: Covid-19 Assessment 03 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:19:24

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'No (N)'	(b) (4) Brett Potthoff (b) (4) (b) (4)	15 Oct 2020 20:44:43

US3572116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:19:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:58:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	03 Sep 2020 22:03:48

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 01:07:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 01:07:09
Data point term sent to Coder	System	25 Feb 2021 01:06:19
User entered 'Depression'	(b) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '01 Dec 2020'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'I'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:30:50
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 01:06:13

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:22
User entered 'USA-US091-2021-mRNA-1273-P301000020'	System	27 Apr 2021 13:08:06
User entered 'New'	(b) (4), (b) (6)	27 Apr 2021 13:08:06

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 19:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 19:34:42
Data point term sent to Coder	System	26 Apr 2021 19:33:54
User entered 'suicide attempt'	Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:32
	(b) (4)	
Signature has been broken.	Maria Candelario (b) (4)	28 Apr 2021 20:18:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	28 Apr 2021 20:18:08
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	26 Apr 2021 19:33:53
	(b) (4)	

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '19 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	26 Apr 2021 19:37:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Apr 2021 19:37:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Apr 2021 19:33:53
User entered '23 Apr 2021'	Jessica McDowell (b) (4) (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Grade 4 (Grade 4)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'l'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'I'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '19 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '23 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	26 Apr 2021 19:37:34
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	26 Apr 2021 19:37:34
User entered empty; reason for change Data Entry Error	Jessica McDowell (b) (4)	26 Apr 2021 19:37:34
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	26 Apr 2021 19:33:53
User entered '0'	Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:32
	(b) (4)	
Signature has been broken.	Maria Candelario (b) (4)	28 Apr 2021 20:20:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	28 Apr 2021 20:20:54
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:32
	(b) (4)	
Signature has been broken.	Maria Candelario (b) (4)	28 Apr 2021 20:20:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Maria Candelario (b) (4)	28 Apr 2021 20:20:54
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica McDowell (b) (4)	26 Apr 2021 19:33:53
	(b) (4)	

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'l'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jessica McDowell (b) (4)	26 Apr 2021 19:37:34
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '2nd suicide attempt. 1st in march but subject doesn't remember exact dates.'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 19:33:53

US3572116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 19:33:53

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:19:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:58:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	03 Sep 2020 22:04:05

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 22:05:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 22:05:45
Data point term sent to Coder	System	03 Sep 2020 22:05:04
User entered 'melatonin'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM). Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per source there is not a medical condition listed that would indicate the use of melatonin. ' (Site from DM). User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (u) (4), (b) (6) (b) (4), (b) (6)	08 Feb 2021 03:30:35 04 Feb 2021 22:39:50
User entered 'sleep'	Jessica McDowell (b) (4) (b) (4)	09 Oct 2020 03:09:20 03 Sep 2020 22:04:41

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered '5' reason for change: New Information	Jasmine Ali (b) (4)	10 Sep 2020 20:48:45
	(b) (4)	
User entered '2.5'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'mg (mg)'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Jasmine Ali (b) (4)	10 Sep 2020 20:48:45
New Information	(b) (4)	
User entered 'once (ONCE)'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'Oral (ORAL)'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'I'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	03 Sep 2020 22:04:41
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 22:04:41

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 22:04:41

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 22:04:41

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 16:06:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 16:06:55
Data point term sent to Coder	System	10 Mar 2021 15:50:50
Data point term sent to Coder	System	10 Mar 2021 15:49:49
Coding entries removed.	Alisha Lutat (b) (4)	10 Mar 2021 15:49:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 04:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 04:02:47
Data point term sent to Coder	System	10 Sep 2020 20:49:40
User entered 'Ibuprofen'	Jasmine Ali (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR RQ: Response noted, however indicated condition is not recorded in MH or AE eCRF. Please review and reconcile.' (Site from DM).	(b) (4) (u) (4), (b) (6)	15 Mar 2021 06:50:22
Query 'Per DM CLR RQ: Response noted, however indicated condition is not recorded in MH or AE eCRF. Please review and reconcile.' answered with 'as this headache was a solicited event it did not meet AE reporting criteria and thus is not listed on AE eCRF' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 22:05:44
User opened query 'Per DM CLR RQ: Response noted, however indicated condition is not recorded in MH or AE eCRF. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 09:31:02
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 09:31:02
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'Indication updated headache' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	10 Mar 2021 15:50:35
User entered 'HEADACHE' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	10 Mar 2021 15:50:28
User entered 'PAIN due to HEADACHE' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	10 Mar 2021 15:49:31
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:16:54
User entered 'Pain/Headache'	Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 05:39:19
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	15 Feb 2021 19:00:51
' answered with 'dosage updated' (Site from DM).		
User entered '200' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:59:30
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	09 Oct 2020 03:09:35
' (Site from DM).		
User entered 'I'	Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (e.g., mg). Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	11 Mar 2021 09:28:51
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (e.g., mg). Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'dosage updated to mg ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	10 Mar 2021 15:50:51
User entered 'mg (mg)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	10 Mar 2021 15:49:31
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (e.g., mg). Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:17:17
User entered 'tablet (TABLET)'	Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'as needed (PRN)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Oral (ORAL)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'l'	(b) (4) Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding solicited event has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 03:06:09
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding solicited event has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	Alisha Lutat (b) (4) (b) (4)	25 Mar 2021 15:08:16
' answered with 'Data updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	25 Mar 2021 15:08:06
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding solicited event has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:24:09
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 15:08:06
User entered empty.	Alisha Lutat (b) (4)	10 Sep 2020 20:49:19
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User entered empty.	System	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User entered empty.	System	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:40:08
User entered empty.	System	10 Sep 2020 20:49:19

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: BENZOCAINE, PRODUCTSYNONYM: ORAJEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 05:43:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 05:43:54
Data point term sent to Coder	System	17 Sep 2020 20:34:41
User entered 'Orajel'	Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	17 Feb 2021 07:23:14
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated as per query resolution' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 23:06:47
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:09:31
User entered 'Oral pain'	Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'I'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Other (OTHER)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'application'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'as needed (PRN)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Topical (TOPICAL)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'UN UNK 2019'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 20:34:27

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Dec 2020 22:56:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 22:56:26
Data point term sent to Coder	System	29 Dec 2020 22:55:54
User entered 'sertraline'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User closed query 'Per DM CLR RQ: Response noted. However MH of bipolar disorder is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (u) (4), (b) (6)	26 Feb 2021 06:01:46
Query 'Per DM CLR RQ: Response noted. However MH of bipolar disorder is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE added to eCRF' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:06:43
User opened query 'Per DM CLR RQ: Response noted. However MH of bipolar disorder is not ongoing. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 04:04:12
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 04:04:12
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Patient has a history of bipolar disorder, which includes episodes of depression.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 21:47:07
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:49:41
User entered 'depression'	Jessica McDowell (b) (4) (b) (4)	29 Dec 2020 22:55:28

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered '50'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'mg (mg)'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'once daily (QD)'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'Oral (ORAL)'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered '15 Dec 2020'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered '0'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered empty.	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
	(b) (4)	
User entered 'No (N)'	Jessica McDowell (b) (4)	29 Dec 2020 22:55:28
	(b) (4)	

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Dec 2020 22:55:28

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Dec 2020 22:55:28

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Dec 2020 22:55:28

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 20:02:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 20:02:45
Data point term sent to Coder	System	26 Apr 2021 20:02:05
User entered 'hydroxyzine'	Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'anxiety'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '25'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'mg (mg)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'as needed (PRN)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Oral (ORAL)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '20 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 20:01:52

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 20:03:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 20:03:55
Data point term sent to Coder	System	26 Apr 2021 20:03:06
User entered 'vitamin D3'	Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'vitamin'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '2500'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'mg (mg)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'once daily (QD)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Oral (ORAL)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '20 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 20:02:40
User entered 'No (N)' reason for change: Data Entry Error	Jessica McDowell (b) (4)	26 Apr 2021 20:02:40
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 20:02:36
User entered empty.	Jessica McDowell (b) (4)	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 20:02:36

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: ASENAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Apr 2021 00:30:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 00:30:54
Data point term sent to Coder	System	26 Apr 2021 20:04:07
User entered 'asenapine'	Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'prevents alcohol cravings'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'unknown'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'mg (mg)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'once daily (QD)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Oral (ORAL)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '20 Apr 2021'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '0'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered empty.	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 20:03:33

US3572116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:19:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:29:23
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	03 Sep 2020 22:04:49

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'USA-US091-2021-MRNA-1273-P301000020'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Milton'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Haber'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered '2344 Laguna Del Mar, Suite 201'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Laredo'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'TX'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered '78041'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 12:47:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'US'	(b) (4) System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 12:47:31
User entered '1'	System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'USA-US091-2021-MRNA-1273-P301000020'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Milton'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Haber'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered '2344 Laguna Del Mar, Suite 201'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Laredo'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'TX'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered '78041'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 12:47:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'US'	(b) (4) System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 12:47:31
User entered '1'	System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:19:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered '27/Apr/2021 08:08'	(b) (4) System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:19:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 12:47:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'I'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'USA-US091-2021-MRNA-1273-P301000020'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Yes (Y)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'No (N)'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Milton'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Haber'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered '2344 Laguna Del Mar, Suite 201'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'Laredo'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered 'TX'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 13:08:38
User entered '78041'	System	27 Apr 2021 13:08:06

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 12:47:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:07:12
User entered 'US'	(b) (4) System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 12:47:31
User entered '1'	System	27 Apr 2021 13:08:44

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:19:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:35
User entered '29/Apr/2021 07:47'	(b) (4) System	29 Apr 2021 12:47:31

US3572116

Folder: SAE USA-US091-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:19:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	29 Apr 2021 15:47:35
User entered 'I'	(b) (4) (u) (4), (b) (6)	29 Apr 2021 12:47:31