

US3172349 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:37:17

All time stamps listed in this document are displayed in GMT

US3172349

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

[Participant ID](#)

US3172349

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

US3172349

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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

Visit date (dd MMM yyyy)	26 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3172349

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	35
Age Units	YEARS
Age (Derived)	35
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 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 type="radio"/> Amendment 3 <input checked="" 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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:34:01

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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) 17 Feb 2021 13:34:01

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Condition	RIGHT OVARIAN CYST BENIGN
Start date (dd MMM yyyy)	UN AUG 2019
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 SEP 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	SEP 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	04 APR 2017
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)	04 APR 2017
Stop date completely unknown	False
Start Month and Year (derived)	APR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	APR 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:34:01

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:03 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:03
Height (<i>xxx.x</i>)	168.0 cm
Weight (<i>xxx.x</i>)	57.9 kg
BMI (<i>xxx.x</i>)	20.51446 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Date of assessment (dd MMM yyyy) 26 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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 26 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:34:01

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:34:01

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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

Visit date (dd MMM yyyy)	26 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108687

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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)	26 AUG 2020
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:03
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:46
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 13:16

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) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	12:55 (24 HR)
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Collection date and time (derived)	26 AUG 2020 12:55
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US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:52	26 AUG 2020 12:52
Nasopharyngeal Swab 2	No		

US3172349

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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: 09 Jun 2021 15:37:17

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

98.6 °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

26 AUG 2020 14:04

PC Open Date & Time

26 AUG 2020 13:36

PC Close Date & Time

26 AUG 2020 16:06

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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 98.6 °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	26 AUG 2020 23:25
PC Open Date & Time	26 AUG 2020 17:01
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

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 ☒

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 12:00

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 15:39

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

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 29 AUG 2020 18:18

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 30 AUG 2020 20:20

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 13:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 14:05

PC Open Date & Time

26 AUG 2020 13:36

PC Close Date & Time

26 AUG 2020 16:06

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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 AUG 2020 23:26

PC Open Date & Time

26 AUG 2020 17:01

PC Close Date & Time

27 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

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

27 AUG 2020 12:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

28 AUG 2020 15:39

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

29 AUG 2020 18:18

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

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

30 AUG 2020 20:20

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

31 AUG 2020 13:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

01 SEP 2020 16:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 14:05
PC Open Date & Time	26 AUG 2020 13:36
PC Close Date & Time	26 AUG 2020 16:06

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 23:26
PC Open Date & Time	26 AUG 2020 17:01
PC Close Date & Time	27 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

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)

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 15:40
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

52 of 1602

EAB) (1725)

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:20
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

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)

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:21
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

56 of 1602

EAB) (1725)

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 13:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

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 ☒

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 16:44
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3172349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

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

Visit date (dd MMM yyyy)	23 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:40
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	23 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3172349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

23 SEP 2020 13:20

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	23 SEP 2020 13:52
Nasopharyngeal Swab 2	No		

US3172349

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

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

Visit date (dd MMM yyyy)	28 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:37 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:37
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172349

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

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.

US3172349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

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

Collection date (dd MMM yyyy)	28 OCT 2020
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Collection time (00:00-23:59)	12:16 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 OCT 2020 12:16
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US3172349

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:02

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 OCT 2020 01:00:18
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

02 NOV 2020 10:30:42

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 20:29:19
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 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	20 NOV 2020 00:32:27
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 00:10:02

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

04 DEC 2020 00:02:17

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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	11 DEC 2020 09:09:47
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 08:17:45

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

25 DEC 2020 12:21:16

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

01 JAN 2021 00:38:51

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 00:02:09

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

15 JAN 2021 07:20:21

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 15:35:42

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 00:08:45

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

05 FEB 2021 08:43:40

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

12 FEB 2021 09:17:45

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

19 FEB 2021 01:03:09

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 06:01:11

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 00:03:06
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

15 MAR 2021 08:10:49

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 222

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 229

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 236

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

23 APR 2021 23:55:08

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 00:02:40

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2021 00:01
Patient Cloud Close Date & Time	10 AUG 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	31 AUG 2021 23:59
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US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐
Yes ☐

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 530

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐
Yes ☐

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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°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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 712

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐ Yes ☐

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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="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"/>

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

Patient Cloud Open Date & Time	14 OCT 2022 00:01
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Patient Cloud Close Date & Time	18 OCT 2022 23:59
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US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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 ☐ Yes ☐

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

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3172349

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:37:17

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		28 FEB 2021 06:01:31

US3172349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 14:00:21

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:00:21

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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 _____

US3172349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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)	

US3172349

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

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.

US3172349

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:32:50

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172349

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172349

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172349

Folder: Covid-19 Assessment 26 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:37:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **09 Mar 2021 14:43:19**

Generated On: 09 Jun 2021 15:37:17

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 14:43:19

Generated On: 09 Jun 2021 15:37:17

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 SICKD28

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 14:43:19

Generated On: 09 Jun 2021 15:37:17

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 14:43:19

Generated On: 09 Jun 2021 15:37:17

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.

US3172349

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Mar 2021 14:43:19

Generated On: 09 Jun 2021 15:37:17

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3172349

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

AEID USA-US118-2020-MRNA-1273-P30
1000005

Adverse event ECTOPIC PREGNANCY ENDED
IN MISCARRIAGE

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 06 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

PRODUCTION RELEASE (v12.003 299 of 1602
EAB) (1725)

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

SUBJECT ARRIVED AT THE CLINIC FOR THEIR DAY 29 VISIT TODAY, 9/23/2020. THE SUBJECT REPORTED A POSITIVE URINE PREGNANCY TEST DURING THIS VISIT. SUBJECT MENTIONED HAVING A MISSED MENSES THIS MONTH AND DECIDED TO PERFORM A URINE PREGNANCY TEST AT HOME YESTERDAY, 22 SEPTEMBER 2020 AND TEST RESULTED POSITIVE. A URINE COLLECTION WAS OBTAINED, AND A PREGNANCY TEST WAS PERFORMED AT THE CLINIC FOR CONFIRMATION AND THE RESULT WAS POSITIVE. ADDITIONALLY, BLOOD WAS COLLECTED FOR A QUALITATIVE/QUANTITATIVE TEST AND SENT OUT TO THE LOCAL LAB FOR A FINAL CONFIRMATION. PLEASE NOTE, SUBJECT REPORTED USING TWO FORMS OF CONTRACEPTION AT THE SCREENING/BASELINE VISIT AND HAD A NEGATIVE RESULT FOR THE URINE PREGNANCY TEST PERFORMED DURING THIS VISIT. SUBJECT RECEIVED THE 1ST STUDY DOSE OF IP ON 8/26/2020. THIS SUBJECT WAS

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

NOT DOSED WITH SECOND
VACCINE TODAY. ALL OTHER
PROCEDURES WERE
COMPLETED FOR DAY 29.
SUBJECT PLANS TO GO
THROUGH WITH THE
PREGNANCY AND AGREES TO
CONTINUE STUDY
PARTICIPATION. SUBJECT WILL
BE FOLLOWED THROUGHOUT
THE STUDY AND PREGNANCY
OUTCOME. ADDITIONAL
DETAILS WILL BE PROVIDED
ONCE THE
QUALITATIVE/QUANTITATIVE
TEST RESULTS ARE RECEIVED
AND CONFIRMS TO BE
POSITIVE.

ON 10/16/2020: SUBJECT
REPORTED HAVING A SMALL
VAGINAL BLEED RELATED TO
A MISCARRIAGE DURING THE
FIRST TRIMESTER. UNDER
OBGYN CARE, MISCARRIAGE
WAS CONFIRMED BY PELVIC
ULTRASOUND AND BLOOD
HCG QUANTITATIVE.
ADDITIONAL INFORMATION
WILL BE PROVIDED ONCE
MEDICAL RECORDS BECOME
AVAILABLE.

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)	

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

AEID

Adverse event

MISCARRIAGE - SECONDARY
TO ECTOPIC PREGNANCY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

06 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 17 Feb 2021 13:34:00

Generated On: 09 Jun 2021 15:37:17

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

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

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

Yes ☒

No ☐

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

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Name of Medication MILI

Prophylaxis Yes ☐
No ☒

Indication CONTRACEPTION

Dose per administration 0.250 / 0.035

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

306 of 1602

EAB) (1725)

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

	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 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Name of Medication ESTARYLLA (NORGESSTIMATE
0.25MG/ETHINYL ESTRADIOL
0.035MG)

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 0.25/0.035

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
06 OCT 2020	REST OBSERVATION	Adverse Event	

US3172349

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 17 Feb 2021 13:34:01

Generated On: 09 Jun 2021 15:37:17

Date of dosing discontinuation (dd MMM yyyy) 23 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

US3172349

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:37:17

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 ☐

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/OCT/2020 13:41
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

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/OCT/2020 16:36
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

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/JAN/2021 09:08
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

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/JAN/2021 11:23
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

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/FEB/2021 20:43
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

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:05
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

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Apr 2021 16:32:49

Generated On: 09 Jun 2021 15:37:17

SAEID	USA-US118-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	
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

US3172349 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172349

Form: Participant Creation

Generated On: 09 Jun 2021 15:37:17

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'US3172349'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:39

US3172349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:41

US3172349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:40

US3172349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:41

US3172349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'SCRN'	System	26 Aug 2020 17:24:41

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:41

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '35'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'YEARS'	System	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '35'	System	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Female (F)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'I'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:24:58

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Aug 2020'	System	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2020'	System	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Amendment 3 (3)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:25

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:40

US3172349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'I'	System	26 Aug 2020 17:25:30

US3172349

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:25:30

US3172349

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:37:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:50

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:51:52
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:39:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:39:51
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	11 Sep 2020 19:55:22
Data point term sent to Coder	System	11 Sep 2020 19:55:22
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	11 Sep 2020 19:55:09
User entered 'RIGHT OVARIAN CYST benign' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Sep 2020 19:55:09
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:27:46

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:59:49
Data point term sent to Coder	System	26 Aug 2020 18:11:42
User entered 'RIGHT OVARIAN CYST'	Mariete Rendon (b) (4)	26 Aug 2020 18:11:32
	(b) (4)	

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'UN Aug 2019'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'UN Sep 2019'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Aug 2019'	System	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2019'	System	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Sep 2019'	System	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2019'	System	26 Aug 2020 18:11:32

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:52
Data point term sent to Coder	System	26 Aug 2020 18:12:46
User entered 'CESAREAN SECTION'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '04 Apr 2017'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '04 Apr 2017'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Apr 2017'	System	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2017'	System	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Apr 2017'	System	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2017'	System	26 Aug 2020 18:12:02

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 23:34:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 23:34:51
Data point term sent to Coder	System	10 Sep 2020 23:33:38
User entered 'headaches'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'un UNK 2008'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Jan 2008'	System	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2008'	System	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered empty.	System	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered empty.	System	10 Sep 2020 23:33:36

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 23:36:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 23:36:44
Data point term sent to Coder	System	10 Sep 2020 23:35:43
User entered 'back pain'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'un UNK 2017'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'Jan 2017'	System	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '2017'	System	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered empty.	System	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered empty.	System	10 Sep 2020 23:34:43

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '12:03'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '168.0' cm	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41
DataPoint set to visible.	System	26 Aug 2020 17:25:30

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '57.9' kg	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41
DataPoint set to visible.	System	26 Aug 2020 17:25:30

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
Amendment Manager: User entered '20.51446'	System	17 Sep 2020 00:03:50
User entered '20.5'	System	26 Aug 2020 18:08:41
DataPoint set to visible.	System	26 Aug 2020 17:25:30

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'kg/m2'	System	26 Aug 2020 18:08:41
DataPoint set to visible.	System	26 Aug 2020 17:25:30

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'bpm'	System	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'breaths/min'	System	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'mmHg'	System	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered 'mmHg'	System	26 Aug 2020 18:08:41

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58

US3172349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58

US3172349

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:24:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:31

US3172349

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:24:41
User entered '26 Aug 2020'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:31

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:17

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:08:59

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Urine (URINE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Negative (NEGATIVE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:09:12

US3172349

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User entered empty.	System	26 Aug 2020 18:09:12

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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[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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

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[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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

US3172349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

US3172349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

[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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

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 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'I'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

US3172349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

US3172349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

US3172349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:11

US3172349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:48

US3172349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:48

US3172349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:48

US3172349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'VISIT1'	System	26 Aug 2020 17:30:48

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:44

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '108687'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 16:44:44

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

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)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:35

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

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)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:35

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:35

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:35

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:26:35

US3172349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:17

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:28:00
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	01 Dec 2020 16:33:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	01 Dec 2020 16:33:10
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 21:38:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:04:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:04:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '26 Aug 2020'	Mariete Rendon (b) (4)	26 Aug 2020 18:10:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '12:03'	Mariete Rendon (b) (4)	26 Aug 2020 18:10:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '69'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'bpm'	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '15'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'breaths/min'	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '97'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '62'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 18:34:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 18:34:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 18:10:08
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '13:46' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '26 Aug 2020 13:46'	System	26 Aug 2020 18:34:09
User entered empty.	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '36.9' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '76' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'bpm'	System	26 Aug 2020 18:34:09
User entered empty.	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '16' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'breaths/min'	System	26 Aug 2020 18:34:09
User entered empty.	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '109' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	26 Aug 2020 18:34:09
User entered empty.	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '72' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	26 Aug 2020 18:34:09
User entered empty.	System	26 Aug 2020 18:10:08

US3172349

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:24:22
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:17

US3172349

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:24:22
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:17

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:49:21
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:49:21
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:49:21
User entered 'Urine (URINE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:49:21
User entered 'Negative (NEGATIVE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:49:21
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	26 Aug 2020 18:10:26

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Aug 2020 17:30:08
	(b) (4)	

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '13:16'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '26 Aug 2020 13:16'	System	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'ONCE'	System	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 17:30:08

US3172349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:17

US3172349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:17

US3172349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '12:55'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:17

US3172349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '26 Aug 2020 12:55'	System	26 Aug 2020 18:12:17

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:37:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '12:52'	Mariete Rendon (b) (4)	26 Aug 2020 18:12:28
	(b) (4)	

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '26 Aug 2020 12:52'	System	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:40:18
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:40:18
User entered '12:52'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	17 Sep 2020 15:40:18
User entered '26 Aug 2020 12:52'	System	26 Aug 2020 18:12:28

US3172349

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:34:16

US3172349

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	26 Aug 2020 18:34:16

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:04:39', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a7a0f892-5e23-4066-b0af-681b48251a4b' User entered 'Yes (Y)'	System	26 Aug 2020 18:04:58
	System	26 Aug 2020 18:04:58

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:04:44', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a7a0f892-5e23-4066-b0af-681b48251a4b' User entered '98.6'	System	26 Aug 2020 18:04:58
	System	26 Aug 2020 18:04:58

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:04:50', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a7a0f892-5e23-4066-b0af-681b48251a4b' User entered 'No (N)'	System	26 Aug 2020 18:04:58
	System	26 Aug 2020 18:04:58

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:04:55', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a7a0f892-5e23-4066-b0af-681b48251a4b' User entered '26 Aug 2020 14:04'	System	26 Aug 2020 18:04:58
	System	26 Aug 2020 18:04:58

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 13:36'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 16:06'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:24:48', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c7db250-f862-4478-afff-1f83dd772d20' User entered 'Yes (Y)'	System	27 Aug 2020 03:25:33
	System	27 Aug 2020 03:25:33

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:25:13', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c7db250-f862-4478-afff-1f83dd772d20' User entered '98.6'	System	27 Aug 2020 03:25:33
	System	27 Aug 2020 03:25:33

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:25:19', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c7db250-f862-4478-afff-1f83dd772d20'	System	27 Aug 2020 03:25:33
User entered 'No (N)'	System	27 Aug 2020 03:25:33

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:25:30', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c7db250-f862-4478-afff-1f83dd772d20' User entered '26 Aug 2020 23:25'	System	27 Aug 2020 03:25:33
	System	27 Aug 2020 03:25:33

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 17:01'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 2'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:00:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '88e72cea-f89a-4898-b6e8-a98cf8e17799' User entered 'No (N)'	System	27 Aug 2020 16:00:51
	System	27 Aug 2020 16:00:51

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:00:40', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '88e72cea-f89a-4898-b6e8-a98cf8e17799'	System	27 Aug 2020 16:00:51
User entered 'No (N)'	System	27 Aug 2020 16:00:51

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:00:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '88e72cea-f89a-4898-b6e8-a98cf8e17799' User entered '27 Aug 2020 12:00'	System	27 Aug 2020 16:00:51
	System	27 Aug 2020 16:00:51

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 3'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:02', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '65d84560-7182-46b4-81a7-bebfa800e8f9' User entered 'Yes (Y)'	System	28 Aug 2020 19:39:30
	System	28 Aug 2020 19:39:30

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:17', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '65d84560-7182-46b4-81a7-bebfa800e8f9' User entered '96.0'	System	28 Aug 2020 19:39:30
	System	28 Aug 2020 19:39:30

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:21', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '65d84560-7182-46b4-81a7-bebfa800e8f9' User entered 'No (N)'	System	28 Aug 2020 19:39:30
	System	28 Aug 2020 19:39:30

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:24', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '65d84560-7182-46b4-81a7-bebfa800e8f9' User entered '28 Aug 2020 15:39'	System	28 Aug 2020 19:39:30
	System	28 Aug 2020 19:39:30

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 4'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:22', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ebb2e185-22b9-4813-a759-ae6cf60fc9fe' User entered 'No (N)'	System	29 Aug 2020 22:18:35
	System	29 Aug 2020 22:18:35

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:29', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ebb2e185-22b9-4813-a759-ae6cf60fc9fe'	System	29 Aug 2020 22:18:35
User entered 'No (N)'	System	29 Aug 2020 22:18:35

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:33', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ebb2e185-22b9-4813-a759-ae6cf60fc9fe' User entered '29 Aug 2020 18:18'	System	29 Aug 2020 22:18:35
	System	29 Aug 2020 22:18:35

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 5'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:12', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '76a25395-23e1-4d3b-ae53-450e322cfc94' User entered 'No (N)'	System	31 Aug 2020 00:20:23
	System	31 Aug 2020 00:20:23

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:15', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '76a25395-23e1-4d3b-ae53-450e322cfc94'	System	31 Aug 2020 00:20:23
User entered 'No (N)'	System	31 Aug 2020 00:20:23

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:22', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '76a25395-23e1-4d3b-ae53-450e322cfc94' User entered '30 Aug 2020 20:20'	System	31 Aug 2020 00:20:23
	System	31 Aug 2020 00:20:23

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 6'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '63908454-dcfe-4f68-aabd-20cd47991abc' User entered 'Yes (Y)'	System	31 Aug 2020 17:27:13
	System	31 Aug 2020 17:27:13

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:16', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '63908454-dcfe-4f68-aabd-20cd47991abc' User entered '98.3'	System	31 Aug 2020 17:27:13
	System	31 Aug 2020 17:27:13

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:19', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '63908454-dcfe-4f68-aabd-20cd47991abc'	System	31 Aug 2020 17:27:13
User entered 'No (N)'	System	31 Aug 2020 17:27:13

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:22', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '63908454-dcfe-4f68-aabd-20cd47991abc' User entered '31 Aug 2020 13:25'	System	31 Aug 2020 17:27:13
	System	31 Aug 2020 17:27:13

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 7'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:07', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8b61a8a1-ceee-410d-b3d5-146cd543a5be' User entered 'Yes (Y)'	System	01 Sep 2020 20:44:18
	System	01 Sep 2020 20:44:18

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:12', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8b61a8a1-ceee-410d-b3d5-146cd543a5be' User entered '96.5'	System	01 Sep 2020 20:44:18
	System	01 Sep 2020 20:44:18

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:14', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8b61a8a1-ceee-410d-b3d5-146cd543a5be' User entered 'No (N)'	System	01 Sep 2020 20:44:18
	System	01 Sep 2020 20:44:18

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:17', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8b61a8a1-ceee-410d-b3d5-146cd543a5be' User entered '01 Sep 2020 16:44'	System	01 Sep 2020 20:44:18
	System	01 Sep 2020 20:44:18

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:02', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ff097dad-d4d7-4ffe-8b60-27b56c918d4e' User entered 'None (1)'	System	26 Aug 2020 18:05:20
	System	26 Aug 2020 18:05:20

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:06', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ff097dad-d4d7-4ffe-8b60-27b56c918d4e' User entered 'No (N)'	System	26 Aug 2020 18:05:20
	System	26 Aug 2020 18:05:20

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:10', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ff097dad-d4d7-4ffe-8b60-27b56c918d4e' User entered 'No (N)'	System	26 Aug 2020 18:05:20
	System	26 Aug 2020 18:05:20

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:14', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ff097dad-d4d7-4ffe-8b60-27b56c918d4e' User entered 'None (1)'	System	26 Aug 2020 18:05:20
	System	26 Aug 2020 18:05:20

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:17', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'ff097dad-d4d7-4ffe-8b60-27b56c918d4e' User entered '26 Aug 2020 14:05'	System	26 Aug 2020 18:05:20
	System	26 Aug 2020 18:05:20

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 13:36'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 16:06'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:25:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '69e2353c-b3d4-4f34-9f0d-2f3ff75ac9d0' User entered 'None (1)'	System	27 Aug 2020 03:26:09
	System	27 Aug 2020 03:26:09

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:25:49', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '69e2353c-b3d4-4f34-9f0d-2f3ff75ac9d0' User entered 'No (N)'	System	27 Aug 2020 03:26:09
	System	27 Aug 2020 03:26:09

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:25:55', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '69e2353c-b3d4-4f34-9f0d-2f3ff75ac9d0'	System	27 Aug 2020 03:26:09
User entered 'No (N)'	System	27 Aug 2020 03:26:09

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:01', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '69e2353c-b3d4-4f34-9f0d-2f3ff75ac9d0'	System	27 Aug 2020 03:26:09
User entered 'None (1)'	System	27 Aug 2020 03:26:09

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:06', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '69e2353c-b3d4-4f34-9f0d-2f3ff75ac9d0' User entered '26 Aug 2020 23:26'	System	27 Aug 2020 03:26:09
	System	27 Aug 2020 03:26:09

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 17:01'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 2'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:00:54', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bbf53579-811a-4f79-aaa9-6bd360a59b30' User entered 'None (1)'	System	27 Aug 2020 16:01:12
	System	27 Aug 2020 16:01:12

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:00:58', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bbf53579-811a-4f79-aaa9-6bd360a59b30' User entered 'No (N)'	System	27 Aug 2020 16:01:12
	System	27 Aug 2020 16:01:12

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bbf53579-811a-4f79-aaa9-6bd360a59b30' User entered 'No (N)'	System	27 Aug 2020 16:01:12
	System	27 Aug 2020 16:01:12

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:02', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bbf53579-811a-4f79-aaa9-6bd360a59b30' User entered 'None (1)'	System	27 Aug 2020 16:01:12
	System	27 Aug 2020 16:01:12

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:05', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bbf53579-811a-4f79-aaa9-6bd360a59b30' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:12
	System	27 Aug 2020 16:01:12

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 3'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:30', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a4523fe9-be05-4191-841a-b9c22f8c6f29'	System	28 Aug 2020 19:39:48
User entered 'None (1)'	System	28 Aug 2020 19:39:48

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:33', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a4523fe9-be05-4191-841a-b9c22f8c6f29' User entered 'No (N)'	System	28 Aug 2020 19:39:48
	System	28 Aug 2020 19:39:48

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a4523fe9-be05-4191-841a-b9c22f8c6f29' User entered 'No (N)'	System	28 Aug 2020 19:39:48
	System	28 Aug 2020 19:39:48

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:41', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a4523fe9-be05-4191-841a-b9c22f8c6f29' User entered 'None (1)'	System	28 Aug 2020 19:39:48
	System	28 Aug 2020 19:39:48

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:39:44', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a4523fe9-be05-4191-841a-b9c22f8c6f29' User entered '28 Aug 2020 15:39'	System	28 Aug 2020 19:39:48
	System	28 Aug 2020 19:39:48

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 4'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:39', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bc1458f8-ffaa-4687-a748-44cefb721243'	System	29 Aug 2020 22:18:56
User entered 'None (1)'	System	29 Aug 2020 22:18:56

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:43', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bc1458f8-ffaa-4687-a748-44cefb721243'	System	29 Aug 2020 22:18:56
User entered 'No (N)'	System	29 Aug 2020 22:18:56

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:48', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bc1458f8-ffaa-4687-a748-44cefb721243'	System	29 Aug 2020 22:18:56
User entered 'No (N)'	System	29 Aug 2020 22:18:56

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:51', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bc1458f8-ffaa-4687-a748-44cefb721243'	System	29 Aug 2020 22:18:56
User entered 'None (1)'	System	29 Aug 2020 22:18:56

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:18:54', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'bc1458f8-ffaa-4687-a748-44cefb721243' User entered '29 Aug 2020 18:18'	System	29 Aug 2020 22:18:56
	System	29 Aug 2020 22:18:56

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 5'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:26', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ed9176-3a4d-492a-8bef-ea714a26b17c' User entered 'None (1)'	System	31 Aug 2020 00:20:44
	System	31 Aug 2020 00:20:44

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:30', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ed9176-3a4d-492a-8bef-ea714a26b17c' User entered 'No (N)'	System	31 Aug 2020 00:20:44
	System	31 Aug 2020 00:20:44

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:32', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ed9176-3a4d-492a-8bef-ea714a26b17c' User entered 'No (N)'	System	31 Aug 2020 00:20:44
	System	31 Aug 2020 00:20:44

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:37', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ed9176-3a4d-492a-8bef-ea714a26b17c' User entered 'None (1)'	System	31 Aug 2020 00:20:44
	System	31 Aug 2020 00:20:44

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:20:41', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ed9176-3a4d-492a-8bef-ea714a26b17c' User entered '30 Aug 2020 20:20'	System	31 Aug 2020 00:20:44
	System	31 Aug 2020 00:20:44

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 6'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:25', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '3ca23b7e-ee7c-4b81-81d3-6dc9bcebd9e8' User entered 'None (1)'	System	31 Aug 2020 17:27:19
	System	31 Aug 2020 17:27:19

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:28', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '3ca23b7e-ee7c-4b81-81d3-6dc9bcebd9e8' User entered 'No (N)'	System	31 Aug 2020 17:27:19
	System	31 Aug 2020 17:27:19

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:32', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '3ca23b7e-ee7c-4b81-81d3-6dc9bcebd9e8' User entered 'No (N)'	System	31 Aug 2020 17:27:19
	System	31 Aug 2020 17:27:19

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '3ca23b7e-ee7c-4b81-81d3-6dc9bcebd9e8' User entered 'None (1)'	System	31 Aug 2020 17:27:19
	System	31 Aug 2020 17:27:19

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:38', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '3ca23b7e-ee7c-4b81-81d3-6dc9bcebd9e8' User entered '31 Aug 2020 13:25'	System	31 Aug 2020 17:27:19
	System	31 Aug 2020 17:27:19

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 7'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:20', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b819a9cb-cbd6-4d63-b617-8dd47597de7a' User entered 'None (1)'	System	01 Sep 2020 20:44:31
	System	01 Sep 2020 20:44:31

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:22', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b819a9cb-cbd6-4d63-b617-8dd47597de7a' User entered 'No (N)'	System	01 Sep 2020 20:44:31
	System	01 Sep 2020 20:44:31

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:24', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b819a9cb-cbd6-4d63-b617-8dd47597de7a' User entered 'No (N)'	System	01 Sep 2020 20:44:31
	System	01 Sep 2020 20:44:31

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:26', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b819a9cb-cbd6-4d63-b617-8dd47597de7a' User entered 'None (1)'	System	01 Sep 2020 20:44:31
	System	01 Sep 2020 20:44:31

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:28', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b819a9cb-cbd6-4d63-b617-8dd47597de7a' User entered '01 Sep 2020 16:44'	System	01 Sep 2020 20:44:31
	System	01 Sep 2020 20:44:31

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:23', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'None (0)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:25', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'None (0)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:28', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'None (0)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:31', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'None (0)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:34', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'None (0)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'None (0)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:40', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered 'No (N)'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T14:05:43', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '53085ac3-d10c-46ba-bbb2-d9803e157e24' User entered '26 Aug 2020 14:05'	System	26 Aug 2020 18:05:47
	System	26 Aug 2020 18:05:47

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 13:36'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 16:06'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:13', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'None (0)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:16', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'None (0)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:20', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'None (0)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:24', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'None (0)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:29', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'None (0)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:34', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'None (0)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:50', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered 'No (N)'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-26T23:26:53', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '35071b84-ceb9-4afa-be74-a9530ee93466' User entered '26 Aug 2020 23:26'	System	27 Aug 2020 03:26:54
	System	27 Aug 2020 03:26:54

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '26 Aug 2020 17:01'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 2'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:10', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'None (0)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:28', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'None (0)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:38', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'None (0)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'None (0)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:47', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'None (0)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:50', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'None (0)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:53', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered 'No (N)'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-27T12:01:56', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '05ca8b30-ab68-489a-8e48-96c958fe68f5' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:02:19
	System	27 Aug 2020 16:02:19

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 3'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:12', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'None (0)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:26', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'None (0)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:41', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'None (0)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'None (0)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:48', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'None (0)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:50', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'None (0)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:54', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered 'No (N)'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-28T15:40:56', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '9ac1a466-dcff-4881-b42d-b7788d8e540a' User entered '28 Aug 2020 15:40'	System	28 Aug 2020 19:40:58
	System	28 Aug 2020 19:40:58

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 4'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:19:19', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8'	System	29 Aug 2020 22:20:07
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:19:28', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered 'None (0)'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:19:34', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered 'None (0)'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:19:39', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered 'None (0)'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:19:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered 'None (0)'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:19:55', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered 'None (0)'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:20:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered 'No (N)'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-29T18:20:06', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '30a4e232-c7fe-4752-8917-418c6e5e38e8' User entered '29 Aug 2020 18:20'	System	29 Aug 2020 22:20:07
	System	29 Aug 2020 22:20:07

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 5'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:09', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99'	System	31 Aug 2020 00:21:37
User entered 'No interference with activity (1)'	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:14', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99' User entered 'None (0)'	System	31 Aug 2020 00:21:37
	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:20', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99' User entered 'None (0)'	System	31 Aug 2020 00:21:37
	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:22', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99' User entered 'None (0)'	System	31 Aug 2020 00:21:37
	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:25', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99' User entered 'None (0)'	System	31 Aug 2020 00:21:37
	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:27', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99' User entered 'None (0)'	System	31 Aug 2020 00:21:37
	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:30', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99'	System	31 Aug 2020 00:21:37
User entered 'No (N)'	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-30T20:21:33', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0abe2d7f-8421-44be-a7f1-167922cf4b99' User entered '30 Aug 2020 20:21'	System	31 Aug 2020 00:21:37
	System	31 Aug 2020 00:21:37

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 6'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:41', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'None (0)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:43', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'None (0)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:44', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'None (0)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:46', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'None (0)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:48', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'None (0)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:49', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'None (0)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:53', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered 'No (N)'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-08-31T13:25:56', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'be468dd8-c9eb-46a9-9ee7-5e39a91fe50a' User entered '31 Aug 2020 13:25'	System	31 Aug 2020 17:27:21
	System	31 Aug 2020 17:27:21

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 7'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:31', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'None (0)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:32', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'None (0)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:34', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'None (0)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'None (0)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:37', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'None (0)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:39', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'None (0)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:49', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered 'No (N)'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-09-01T16:44:51', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41d98ef0-1954-4dd8-8793-bb52c695deea' User entered '01 Sep 2020 16:44'	System	01 Sep 2020 20:44:53
	System	01 Sep 2020 20:44:53

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 17:30:08

US3172349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:36:04

US3172349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '03 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:36:04

US3172349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:36:04

US3172349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:36:04

US3172349

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:36:08

US3172349

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	03 Sep 2020 19:36:08

US3172349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:00

US3172349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '10 Sep 2020'	Jessie Downs (b) (4)	17 Sep 2020 19:40:00
	(b) (4)	

US3172349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:00

US3172349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:00

US3172349

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:19

US3172349

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	17 Sep 2020 19:40:19

US3172349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:35

US3172349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '16 Sep 2020'	Jessie Downs (b) (4)	17 Sep 2020 19:40:35
	(b) (4)	

US3172349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:35

US3172349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:35

US3172349

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:39

US3172349

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	17 Sep 2020 19:40:39

US3172349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:19

US3172349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '23 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:19

US3172349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:19

US3172349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'VISIT2'	System	24 Sep 2020 14:00:19

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '23 Sep 2020'	Mariete Rendon (b) (4)	24 Sep 2020 14:00:50
	(b) (4)	

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '12:40'	Mariete Rendon (b) (4)	24 Sep 2020 14:00:50
	(b) (4)	

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '23 Sep 2020 12:40'	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '36.6' C	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '65'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'bpm'	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '15'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'breaths/min'	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '100'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '62'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:00:50

US3172349

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '23 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:00:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '23 Sep 2020'	Mariete Rendon (b) (4)	24 Sep 2020 13:55:56
	(b) (4)	

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Urine (URINE)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 03:34:37
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Confirmed via urine pregnancy test. Pregnancy test form sent to IQVIA (E-pip.)' (Site from System).	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:59:06
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	24 Sep 2020 13:55:56
User entered 'Positive (POSITIVE)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 13:55:56

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Pregnancy (PREGNANCY)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:17

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:01:07

US3172349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:16

US3172349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:15:53
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Confirmed, Sample shipped on 29SEP20.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:14:12
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 21:01:07
User entered '23 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:16

US3172349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '13:20'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:16

US3172349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '23 Sep 2020 13:20'	System	24 Sep 2020 14:01:16

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:37:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '23 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '13:52'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '23 Sep 2020 13:52'	System	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered empty.	System	24 Sep 2020 14:01:53

US3172349

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:02:04

US3172349

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	24 Sep 2020 14:02:04

US3172349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 18:51:20

US3172349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '30 Sep 2020'	Mariete Rendon (b) (4)	06 Oct 2020 18:51:20
	(b) (4)	

US3172349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	06 Oct 2020 18:51:20
	(b) (4)	

US3172349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 18:51:20

US3172349

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 23:23:38
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 18:39:53
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 18:51:24

US3172349

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '1'	System	16 Oct 2020 23:23:38
User entered empty.	System	07 Oct 2020 18:39:53
User entered '1'	System	06 Oct 2020 18:51:24

US3172349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:23:58

US3172349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '8 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:23:58

US3172349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 23:23:58

US3172349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:23:58

US3172349

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:24:05

US3172349

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	16 Oct 2020 23:24:05

US3172349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:24:22

US3172349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '14 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:24:22

US3172349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 23:24:22

US3172349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:24:22

US3172349

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:01:13
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 14:40:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:25:28

US3172349

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '1'	System	28 Oct 2020 19:01:13
User entered empty.	System	19 Oct 2020 14:40:33
User entered '1'	System	16 Oct 2020 23:25:28

US3172349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:10:55

US3172349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '28 Oct 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:10:55

US3172349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:10:55

US3172349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'VISIT3'	System	28 Oct 2020 19:10:55

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '28 Oct 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '11:37'	Jessie Downs (b) (4)	28 Oct 2020 19:12:36
	(b) (4)	

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '28 Oct 2020 11:37'	System	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '83'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'bpm'	System	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '16'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'breaths/min'	System	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '98'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '67'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'mmHg'	System	28 Oct 2020 19:12:36

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15

US3172349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15

US3172349

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:11:07

US3172349

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:11:07

US3172349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:11:34

US3172349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '28 Oct 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:11:34

US3172349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '12:16'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:11:34

US3172349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '28 Oct 2020 12:16'	System	28 Oct 2020 19:11:34

US3172349

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 21:56:45
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 19:11:39

US3172349

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered '1'	System	18 Nov 2020 21:56:45
User entered empty.	System	28 Oct 2020 19:11:39

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 64'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-10-26T00:59:54', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a3db84fe-e107-4a71-b7a0-8419700ff8a8'	System	26 Oct 2020 05:00:20
User entered 'Yes (Y)'	System	26 Oct 2020 05:00:20

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-10-26T00:59:57', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a3db84fe-e107-4a71-b7a0-8419700ff8a8'	System	26 Oct 2020 05:00:20
User entered 'No (N)'	System	26 Oct 2020 05:00:20

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-10-26T01:00:02', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a3db84fe-e107-4a71-b7a0-8419700ff8a8'	System	26 Oct 2020 05:00:20
User entered 'No (N)'	System	26 Oct 2020 05:00:20

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-10-26T01:00:15', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a3db84fe-e107-4a71-b7a0-8419700ff8a8'	System	26 Oct 2020 05:00:20
User entered 'No (N)'	System	26 Oct 2020 05:00:20

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-10-26T01:00:18', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a3db84fe-e107-4a71-b7a0-8419700ff8a8' User entered '26 Oct 2020 01:00:18'	System	26 Oct 2020 05:00:20
	System	26 Oct 2020 05:00:20

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 71'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-02T10:30:17', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '32ca4c83-f532-45ab-ba65-4faceda61dc2'	System	02 Nov 2020 15:30:47
User entered 'No (N)'	System	02 Nov 2020 15:30:47

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-02T10:30:27', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '32ca4c83-f532-45ab-ba65-4faceda61dc2'	System	02 Nov 2020 15:30:47
User entered 'No (N)'	System	02 Nov 2020 15:30:47

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-02T10:30:42', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '32ca4c83-f532-45ab-ba65-4faceda61dc2' User entered '02 Nov 2020 10:30:42'	System	02 Nov 2020 15:30:47
	System	02 Nov 2020 15:30:47

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered 'Day 78'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-09T20:28:53', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '5b023b41-2448-4778-8b60-02f77f9fa45d' User entered 'No (N)'	System	10 Nov 2020 01:29:21
	System	10 Nov 2020 01:29:21

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-09T20:29:02', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '5b023b41-2448-4778-8b60-02f77f9fa45d' User entered 'No (N)'	System	10 Nov 2020 01:29:21
	System	10 Nov 2020 01:29:21

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-09T20:29:19', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '5b023b41-2448-4778-8b60-02f77f9fa45d' User entered '09 Nov 2020 20:29:19'	System	10 Nov 2020 01:29:21
	System	10 Nov 2020 01:29:21

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 17:30:08

US3172349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:15
Data entry locked.	System	26 Aug 2020 17:30:08
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 17:30:08

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-20T00:32:11', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '2030ad6d-e873-455b-bed9-011a8103c620' User entered 'No (N)'	System	20 Nov 2020 05:32:29

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-20T00:32:15', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '2030ad6d-e873-455b-bed9-011a8103c620'	System	20 Nov 2020 05:32:29
User entered 'No (N)'	System	20 Nov 2020 05:32:29

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-20T00:32:27', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '2030ad6d-e873-455b-bed9-011a8103c620' User entered '20 Nov 2020 00:32:27'	System	20 Nov 2020 05:32:29
	System	20 Nov 2020 05:32:29

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-27T00:09:54', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '533c9050-0649-4b26-9a3a-82431fff187b' User entered 'No (N)'	System	27 Nov 2020 05:10:06
	System	27 Nov 2020 05:10:06

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-27T00:09:59', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '533c9050-0649-4b26-9a3a-82431fff187b' User entered 'No (N)'	System	27 Nov 2020 05:10:06
	System	27 Nov 2020 05:10:06

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-11-27T00:10:02', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '533c9050-0649-4b26-9a3a-82431fff187b' User entered '27 Nov 2020 00:10:02'	System	27 Nov 2020 05:10:06
	System	27 Nov 2020 05:10:06

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-04T00:02:06', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '6759b1c1-00d0-47e9-9ac6-fb6e851ef3bd' User entered 'No (N)'	System	04 Dec 2020 05:02:31
	System	04 Dec 2020 05:02:31

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-04T00:02:09', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '6759b1c1-00d0-47e9-9ac6-fb6e851ef3bd' User entered 'No (N)'	System	04 Dec 2020 05:02:31
	System	04 Dec 2020 05:02:31

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-04T00:02:17', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '6759b1c1-00d0-47e9-9ac6-fb6e851ef3bd' User entered '04 Dec 2020 00:02:17'	System	04 Dec 2020 05:02:31
	System	04 Dec 2020 05:02:31

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-11T09:09:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '541219b5-6044-4e6c-9c22-9f76789819f9' User entered 'No (N)'	System	11 Dec 2020 14:09:49
	System	11 Dec 2020 14:09:49

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-11T09:09:43', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '541219b5-6044-4e6c-9c22-9f76789819f9' User entered 'No (N)'	System	11 Dec 2020 14:09:49
	System	11 Dec 2020 14:09:49

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-11T09:09:47', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '541219b5-6044-4e6c-9c22-9f76789819f9' User entered '11 Dec 2020 09:09:47'	System	11 Dec 2020 14:09:49
	System	11 Dec 2020 14:09:49

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-18T08:17:38', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b0667b39-ddb4-49d0-b284-e792622189bb' User entered 'No (N)'	System	18 Dec 2020 13:17:50
	System	18 Dec 2020 13:17:50

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-18T08:17:41', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b0667b39-ddb4-49d0-b284-e792622189bb'	System	18 Dec 2020 13:17:50
User entered 'No (N)'	System	18 Dec 2020 13:17:50

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-18T08:17:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b0667b39-ddb4-49d0-b284-e792622189bb' User entered '18 Dec 2020 08:17:45'	System	18 Dec 2020 13:17:50
	System	18 Dec 2020 13:17:50

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-25T12:21:06', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0f5331c2-bb8f-4ba2-b4ff-88038ad048c8' User entered 'No (N)'	System	25 Dec 2020 17:21:18
	System	25 Dec 2020 17:21:18

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-25T12:21:10', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0f5331c2-bb8f-4ba2-b4ff-88038ad048c8'	System	25 Dec 2020 17:21:18
User entered 'No (N)'	System	25 Dec 2020 17:21:18

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2020-12-25T12:21:16', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '0f5331c2-bb8f-4ba2-b4ff-88038ad048c8' User entered '25 Dec 2020 12:21:16'	System	25 Dec 2020 17:21:18
	System	25 Dec 2020 17:21:18

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-01T00:38:46', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c1836b5-8447-4eec-b2df-bc5a3b6a3a01' User entered 'No (N)'	System	01 Jan 2021 05:38:53
	System	01 Jan 2021 05:38:53

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-01T00:38:49', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c1836b5-8447-4eec-b2df-bc5a3b6a3a01' User entered 'No (N)'	System	01 Jan 2021 05:38:53
	System	01 Jan 2021 05:38:53

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-01T00:38:51', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '8c1836b5-8447-4eec-b2df-bc5a3b6a3a01' User entered '01 Jan 2021 00:38:51'	System	01 Jan 2021 05:38:53
	System	01 Jan 2021 05:38:53

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-08T00:02:01', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e3050b86-2fcc-4346-abf2-fde2f1a24b26'	System	08 Jan 2021 05:02:22
User entered 'No (N)'	System	08 Jan 2021 05:02:22

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-08T00:02:05', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e3050b86-2fcc-4346-abf2-fde2f1a24b26'	System	08 Jan 2021 05:02:22
User entered 'No (N)'	System	08 Jan 2021 05:02:22

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-08T00:02:09', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e3050b86-2fcc-4346-abf2-fde2f1a24b26' User entered '08 Jan 2021 00:02:09'	System	08 Jan 2021 05:02:22
	System	08 Jan 2021 05:02:22

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-15T07:20:14', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '77580d2b-a0b1-497e-80f6-a0f20e319fa8'	System	15 Jan 2021 12:20:25
User entered 'No (N)'	System	15 Jan 2021 12:20:25

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-15T07:20:17', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '77580d2b-a0b1-497e-80f6-a0f20e319fa8'	System	15 Jan 2021 12:20:25
User entered 'No (N)'	System	15 Jan 2021 12:20:25

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-15T07:20:21', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '77580d2b-a0b1-497e-80f6-a0f20e319fa8' User entered '15 Jan 2021 07:20:21'	System	15 Jan 2021 12:20:25
	System	15 Jan 2021 12:20:25

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-22T15:35:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '332073d6-2ffd-4947-8781-fc41f798cc34'	System	22 Jan 2021 20:35:45
User entered 'No (N)'	System	22 Jan 2021 20:35:45

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-22T15:35:39', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '332073d6-2ffd-4947-8781-fc41f798cc34'	System	22 Jan 2021 20:35:45
User entered 'No (N)'	System	22 Jan 2021 20:35:45

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-22T15:35:42', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '332073d6-2ffd-4947-8781-fc41f798cc34' User entered '22 Jan 2021 15:35:42'	System	22 Jan 2021 20:35:45
	System	22 Jan 2021 20:35:45

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-29T00:08:37', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '47eab98d-f234-419b-87eb-ecaa90eca1b5'	System	29 Jan 2021 05:08:49
User entered 'No (N)'	System	29 Jan 2021 05:08:49

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-29T00:08:41', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '47eab98d-f234-419b-87eb-ecaa90eca1b5'	System	29 Jan 2021 05:08:49
User entered 'No (N)'	System	29 Jan 2021 05:08:49

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-01-29T00:08:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '47eab98d-f234-419b-87eb-ecaa90eca1b5' User entered '29 Jan 2021 00:08:45'	System	29 Jan 2021 05:08:49
	System	29 Jan 2021 05:08:49

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-05T08:43:33', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e70f1c56-d246-4187-9699-4f008003fe74' User entered 'No (N)'	System	10 Feb 2021 14:49:27

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-05T08:43:36', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e70f1c56-d246-4187-9699-4f008003fe74' User entered 'No (N)'	System	10 Feb 2021 14:49:27

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-05T08:43:40', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e70f1c56-d246-4187-9699-4f008003fe74' User entered '05 Feb 2021 08:43:40'	System	10 Feb 2021 14:49:27
	System	10 Feb 2021 14:49:27

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-12T09:17:39', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41dac0dc-eb91-4a8f-9325-d73bb437d3be' User entered 'No (N)'	System	12 Feb 2021 14:17:47
	System	12 Feb 2021 14:17:47

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-12T09:17:42', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41dac0dc-eb91-4a8f-9325-d73bb437d3be' User entered 'No (N)'	System	12 Feb 2021 14:17:47
	System	12 Feb 2021 14:17:47

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-12T09:17:45', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '41dac0dc-eb91-4a8f-9325-d73bb437d3be' User entered '12 Feb 2021 09:17:45'	System	12 Feb 2021 14:17:47
	System	12 Feb 2021 14:17:47

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-19T01:03:04', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '77866b54-7404-4210-b2a3-72ea52c4c50e'	System	19 Feb 2021 06:03:12
User entered 'No (N)'	System	19 Feb 2021 06:03:12

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-19T01:03:06', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '77866b54-7404-4210-b2a3-72ea52c4c50e'	System	19 Feb 2021 06:03:12
User entered 'No (N)'	System	19 Feb 2021 06:03:12

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-19T01:03:09', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '77866b54-7404-4210-b2a3-72ea52c4c50e' User entered '19 Feb 2021 01:03:09'	System	19 Feb 2021 06:03:12
	System	19 Feb 2021 06:03:12

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-28T01:01:05-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '67cbf97b-a82f-496c-ae65-61d851bd4cc6'	System	28 Feb 2021 06:01:15
User entered 'No (N)'	System	28 Feb 2021 06:01:15

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-28T01:01:08-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '67cbf97b-a82f-496c-ae65-61d851bd4cc6'	System	28 Feb 2021 06:01:15
User entered 'No (N)'	System	28 Feb 2021 06:01:15

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-28T01:01:11-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '67cbf97b-a82f-496c-ae65-61d851bd4cc6'	System	28 Feb 2021 06:01:15
User entered '28 Feb 2021 06:01:11'	System	28 Feb 2021 06:01:15

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-03-05T00:03:00-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'cc3a170f-23f9-48e2-a10c-b14256965f2f' User entered 'No (N)'	System	05 Mar 2021 05:04:15
	System	05 Mar 2021 05:04:15

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-03-05T00:03:02-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'cc3a170f-23f9-48e2-a10c-b14256965f2f' User entered 'No (N)'	System	05 Mar 2021 05:04:15
	System	05 Mar 2021 05:04:15

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-03-05T00:03:06-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'cc3a170f-23f9-48e2-a10c-b14256965f2f' User entered '05 Mar 2021 00:03:06'	System	05 Mar 2021 05:04:15
	System	05 Mar 2021 05:04:15

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-03-15T08:10:42-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a077bdff-8a0c-43ab-b05a-718cbee3f627'	System	15 Mar 2021 12:10:52
User entered 'No (N)'	System	15 Mar 2021 12:10:52

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Have you been exposed to someone with 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 (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-03-15T08:10:46-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a077bdff-8a0c-43ab-b05a-718cbee3f627'	System	15 Mar 2021 12:10:52
User entered 'No (N)'	System	15 Mar 2021 12:10:52

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-03-15T08:10:49-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'a077bdf-8a0c-43ab-b05a-718cbee3f627'	System	15 Mar 2021 12:10:52
User entered '15 Mar 2021 08:10:49'	System	15 Mar 2021 12:10:52

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (FDE6B7D5-FED3-41CB-A2D2-E25B7697EB9F)', Time: '2021-04-23T23:55:02-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b7d051f0-c84d-4445-9ae2-50c58b523176'	System	24 Apr 2021 03:56:44
User entered 'No (N)'	System	24 Apr 2021 03:56:44

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (FDE6B7D5-FED3-41CB-A2D2-E25B7697EB9F)', Time: '2021-04-23T23:55:04-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b7d051f0-c84d-4445-9ae2-50c58b523176'	System	24 Apr 2021 03:56:44
User entered 'No (N)'	System	24 Apr 2021 03:56:44

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FDE6B7D5-FED3-41CB-A2D2-E25B7697EB9F)', Time: '2021-04-23T23:55:08-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'b7d051f0-c84d-4445-9ae2-50c58b523176'	System	24 Apr 2021 03:56:44
User entered '23 Apr 2021 23:55:08'	System	24 Apr 2021 03:56:44

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[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 (FDE6B7D5-FED3-41CB-A2D2-E25B7697EB9F)', Time: '2021-04-30T00:02:30-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '90703ffb-b962-4660-b62e-a4d1a3c97bee' User entered 'No (N)'	System	30 Apr 2021 04:04:19
	System	30 Apr 2021 04:04:19

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

Have you been exposed to someone with 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 (FDE6B7D5-FED3-41CB-A2D2-E25B7697EB9F)', Time: '2021-04-30T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '90703ffb-b962-4660-b62e-a4d1a3c97bee' User entered 'No (N)'	System	30 Apr 2021 04:04:19

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FDE6B7D5-FED3-41CB-A2D2-E25B7697EB9F)', Time: '2021-04-30T00:02:40-04:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: '90703ffb-b962-4660-b62e-a4d1a3c97bee' User entered '30 Apr 2021 00:02:40'	System	30 Apr 2021 04:04:19
	System	30 Apr 2021 04:04:19

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:15:57

US3172349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:15:57
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:15:57

US3172349

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:37:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:56:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-28T01:01:22-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e741d391-ff19-4316-a1f8-381e6cc8c197'	System	28 Feb 2021 06:01:41
User entered 'No (N)'	System	28 Feb 2021 06:01:41

US3172349

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:37:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:56:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0CFFF0A2-A061-4FE7-9E97-080F038E5A93)', Time: '2021-02-28T01:01:31-05:00', User OID: 'PatientReportedOutcome (US3172349)', ODM File OID: 'e741d391-ff19-4316-a1f8-381e6cc8c197' User entered '28 Feb 2021 06:01:31'	System	28 Feb 2021 06:01:41
	System	28 Feb 2021 06:01:41

US3172349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 21:56:55

US3172349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '18 Nov 2020'	Mariete Rendon (b) (4)	18 Nov 2020 21:56:55
	(b) (4)	

US3172349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	18 Nov 2020 21:56:55
	(b) (4)	

US3172349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 21:56:55

US3172349

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 21:58:22

US3172349

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:15
User entered 'I'	System	18 Nov 2020 21:58:22

US3172349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Dec 2020 15:17:01

US3172349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '22 Dec 2020'	Jessie Downs (b) (4) (b) (4)	24 Dec 2020 15:17:01

US3172349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	24 Dec 2020 15:17:01

US3172349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Dec 2020 15:17:01

US3172349

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Dec 2020 15:17:05

US3172349

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User entered 'I'	System	24 Dec 2020 15:17:05

US3172349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Jan 2021 17:10:22

US3172349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '20 Jan 2021'	Jessie Downs (b) (4) (b) (4)	21 Jan 2021 17:10:22

US3172349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	21 Jan 2021 17:10:22

US3172349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Jan 2021 17:10:22

US3172349

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Jan 2021 17:10:11

US3172349

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User entered 'I'	System	21 Jan 2021 17:10:11

US3172349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 16:18:01

US3172349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:21
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 16:18:01

US3172349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:21
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 16:18:01

US3172349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 16:18:01

US3172349

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 16:18:06

US3172349

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:41:02
User entered 'I'	System	24 Feb 2021 16:18:06

US3172349

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	21 Apr 2021 20:41:46

US3172349

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 20:41:46

US3172349

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:42:00

US3172349

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered '21 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 20:42:00

US3172349

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	21 Apr 2021 20:42:00

US3172349

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:42:00

US3172349

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	21 Apr 2021 20:42:04

US3172349

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 20:42:04

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:37:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:37:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:17

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:52

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:52

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:52

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:17

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	03 Mar 2021 15:55:52

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 15:55:56

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:01

US3172349

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:01

US3172349

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:37:17

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:05

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:37:17

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 15:56:05

US3172349

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:37:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:17:01
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:40:59

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:00
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	22 Oct 2020 13:40:56

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As it was reported, the outcome of the pregnancy was spontaneous abortion. Please update the event term from "ectopic pregnancy ended in miscarriage" to "Spontaneous abortion".' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 19:52:36
User closed query 'PV Query: Please consider splitting the event term ECTOPIC PREGNANCY ENDED IN MISCARRIAGE into separate events of Ectopic Pregnancy and Spontaneous abortion.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:04:50
Query 'PV Query: Please consider splitting the event term ECTOPIC PREGNANCY ENDED IN MISCARRIAGE into separate events of Ectopic Pregnancy and Spontaneous abortion.' answered with 'Both Adverse Events were split into two separate events.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 13:22:51
User opened query 'PV Query: Please consider splitting the event term ECTOPIC PREGNANCY ENDED IN MISCARRIAGE into separate events of Ectopic Pregnancy and Spontaneous abortion.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 20:56:35
User closed query 'For coding purposes, please split ECTOPIC PREGNANCY ENDED IN MISCARRIAGE into separate entries. 1. ECTOPIC PREGNANCY and 2. [ECTOPIC PREGNANCY ENDED IN] MISCARRIAGE' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 13:17:35
User closed query 'PV Query- Please confirm if the diagnosis should be spontaneous abortion or ectopic pregnancy. There is no clear diagnosis mentioned in the discharge summary.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:07:22
Query 'PV Query- Please confirm if the diagnosis should be spontaneous abortion or ectopic pregnancy. There is no clear diagnosis mentioned in the discharge summary.' answered with 'spontaneous abortion' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 16:18:56
User opened query 'PV Query- Please confirm if the diagnosis should be spontaneous abortion or ectopic pregnancy. There is no clear diagnosis mentioned in the discharge summary.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:10:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purposes, please split ECTOPIC PREGNANCY ENDED IN MISCARRIAGE into separate entries. 1. ECTOPIC PREGNANCY and 2. [ECTOPIC PREGNANCY ENDED IN] MISCARRIAGE' answered with 'AE was separated into separate entries.' (Site from Coder).	Jessie Downs (b) (4)	30 Jan 2021 19:49:07
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Maternal complications of pregnancy NEC, PT: Ectopic pregnancy, LLT: Ectopic pregnancy - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 10:49:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 10:49:16
User opened query 'For coding purposes, please split ECTOPIC PREGNANCY ENDED IN MISCARRIAGE into separate entries. 1. ECTOPIC PREGNANCY and 2. [ECTOPIC PREGNANCY ENDED IN] MISCARRIAGE' (Site from Coder).	(b) (4), (b) (6)	22 Jan 2021 10:48:20
Data point term sent to Coder	System	19 Jan 2021 20:10:04
DataPoint Un-verified.	Jessie Downs (b) (4)	19 Jan 2021 20:09:55
Coding entries removed.	Jessie Downs (b) (4)	19 Jan 2021 20:09:55
User entered 'ectopic pregnancy ended in miscarriage' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Jan 2021 20:09:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Miscarriage - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:59:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:59:07
User closed query 'PV Query: Please consider updating the event term to "Spontaneous abortion."' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:36:10
Data point term sent to Coder	System	28 Oct 2020 19:44:12
Query 'PV Query: Please consider updating the event term to "Spontaneous abortion."' answered with 'Data was updated.' (Site from Safety).	Jessie Downs (b) (4)	28 Oct 2020 19:43:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Jessie Downs (b) (4)	28 Oct 2020 19:43:38
	(b) (4)	
User entered 'Miscarriage' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Oct 2020 19:43:38
	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to "Spontaneous abortion." (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 15:15:47
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLG: Maternal complications of pregnancy, HLT: Haemorrhagic complications of pregnancy, PT: Haemorrhage in pregnancy, LLT: Hemorrhage in early pregnancy - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 20:15:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 20:15:29
	(b) (4)	
Data point term sent to Coder	System	09 Oct 2020 19:19:39
User entered 'SMALL UTERINE BLEEDING FIRST TRIMESTER OF PREGNANCY'	Jessie Downs (b) (4)	09 Oct 2020 19:18:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:50
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '06 Oct 2020'	Jessie Downs (b) (4)	09 Oct 2020 19:18:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 19:19:09
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	09 Oct 2020 19:19:09
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 19:18:57
User entered '10:00'	Jessie Downs (b) (4)	09 Oct 2020 19:18:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:19:09
User entered '06 Oct 2020 10:00'	System	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 14:23:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:50
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '13 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 14:23:19
User entered empty.	Jessie Downs (b) (4)	09 Oct 2020 19:18:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User closed query 'Urgent PV Query: As the outcome was considered as a spontaneous abortion (SAE per protocol) please consider updating this event from a non serious event to a SAE, and report applicable SAE fields (causality, seriousness criterion, updated term, etc).'	(b) (4), (b) (6)	22 Oct 2020 16:44:48
(Site from Safety).		
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.'	System	21 Oct 2020 22:41:06
(Site from System).		
Query 'Urgent PV Query: As the outcome was considered as a spontaneous abortion (SAE per protocol) please consider updating this event from a non serious event to a SAE, and report applicable SAE fields (causality, seriousness criterion, updated term, etc).'	Mariete Rendon (b) (4)	21 Oct 2020 16:41:17
answered with 'Data updated as requested' (Site from Safety).	(b) (4)	
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.'	System	21 Oct 2020 16:40:52
(Site from System).		
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 16:40:52
	(b) (4)	
User opened query 'Urgent PV Query: As the outcome was considered as a spontaneous abortion (SAE per protocol) please consider updating this event from a non serious event to a SAE, and report applicable SAE fields (causality, seriousness criterion, updated term, etc).'	(b) (4), (b) (6)	19 Oct 2020 22:20:52
(Site from Safety).		
User entered 'No (N)'	Jessie Downs (b) (4)	09 Oct 2020 19:18:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

US3172349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:41:06
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:41:06
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:41:06
User entered '1'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mariete Rendon (b) (4)	14 Oct 2020 14:23:19
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4)	09 Oct 2020 19:18:57
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "ULTRASOUND." However, this information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:17:11
Query 'Per DM CLR: Narrative indicates that subject had "ULTRASOUND." However, this information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'pending' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:21:18
Query 'PV Query- Please confirm if the diagnosis should be spontaneous abortion or ectopic pregnancy. There is no clear diagnosis mentioned in the discharge summary.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:09:59
User opened query 'PV Query- Please confirm if the diagnosis should be spontaneous abortion or ectopic pregnancy. There is no clear diagnosis mentioned in the discharge summary.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:09:35
User opened query 'Per DM CLR: Narrative indicates that subject had "ULTRASOUND." However, this information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:28:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'PV Query: Thank you for sending the emergency department discharge summary. Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:39:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for sending the emergency department discharge summary. Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records sent ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	04 Feb 2021 17:04:39
User opened query 'PV Query: Thank you for sending the emergency department discharge summary. Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 21:46:57
User closed query 'PV Query: Thank you for sending the emergency department discharge summary. Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:27:40
Query 'PV Query: Thank you for sending the emergency department discharge summary. Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records sent.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 19:34:51
User opened query 'PV Query: Thank you for sending the emergency department discharge summary. Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:40:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:37:01

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 23:01:16
Query 'PV Query: Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'OB/GYN records for this subject has been emailed to IQVIA. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:22:18
User opened query 'PV Query: Please send a OB/GYN medical record with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:02:19
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:36:30
User closed query 'PV Query: The subject had several abortions in previous years (1 abortion 2004; 8 abortions 2007-2015; 1 abortion 2018; 1 abortion 2019). Were these abortions spontaneous or induced?' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:36:21
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Subject was never at the hospital. Subject went to her OBGYN office.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:20:29

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject had several abortions in previous years (1 abortion 2004; 8 abortions 2007-2015; 1 abortion 2018; 1 abortion 2019). Were these abortions spontaneous or induced?' answered with 'Induced' (Site from Safety).	Jessie Downs (b) (4)	28 Oct 2020 20:19:44
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 15:16:24
User opened query 'PV Query: The subject had several abortions in previous years (1 abortion 2004; 8 abortions 2007-2015; 1 abortion 2018; 1 abortion 2019). Were these abortions spontaneous or induced?' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 15:16:06
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 16:45:09
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 16:45:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject arrived at the clinic for their day 29 visit today, 9/23/2020. The subject reported a positive urine pregnancy test during this visit. Subject mentioned having a missed menses this month and decided to perform a urine pregnancy test at home yesterday, 22 September 2020 and test resulted positive. A urine collection was obtained, and a pregnancy test was performed at the clinic for confirmation and the result was positive. Additionally, blood was collected for a qualitative/quantitative test and sent out to the local lab for a final confirmation. Please note, subject reported using two forms of contraception at the screening/baseline visit and had a negative result for the urine pregnancy test performed during this visit. Subject received the 1st study dose of IP on 8/26/2020. This subject was not dosed with second vaccine today. All other procedures were completed for day 29. Subject plans to go through with the pregnancy and agrees to continue study participation. Subject will be followed throughout the study and pregnancy outcome. Additional details will be provided once the qualitative/quantitative test results are received and confirms to be positive. On 10/16/2020: Subject reported having a small vaginal bleed related to a miscarriage during the first trimester. Under OBGYN care, miscarriage was confirmed by pelvic ultrasound and blood HCG Quantitative. Additional information will be provided once medical records become available.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 16:45:09
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 16:40:52
User entered empty.	Jessie Downs (b) (4)	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:40:52
User entered '0'	System	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 19:18:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Miscarriage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 13:15:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 13:15:23
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Maternal complications of pregnancy NEC, PT: Ectopic pregnancy, LLT: Ectopic pregnancy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 22:37:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 22:37:48
Data point term sent to Coder	System	30 Jan 2021 19:43:01
User entered 'Miscarriage - secondary to ectopic pregnancy'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	30 Jan 2021 19:42:16
User entered '06 Oct 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:16
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	30 Jan 2021 19:42:01
User entered '06 Oct 2021'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Jan 2021 19:48:16
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	30 Jan 2021 19:48:16
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Jan 2021 19:42:01
User entered '10:00'	Jessie Downs (b) (4)	30 Jan 2021 19:42:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User entered empty.	System	30 Jan 2021 19:48:16
User entered '06 Oct 2020 10:00'	System	30 Jan 2021 19:42:16
User entered '06 Oct 2021 10:00'	System	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	30 Jan 2021 19:42:16
User entered '13 Oct 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:16
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	30 Jan 2021 19:42:01
User entered '13 Oct 2021'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	30 Jan 2021 19:48:16
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	30 Jan 2021 19:48:16
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	30 Jan 2021 19:42:01
User entered '12:00'	Jessie Downs (b) (4)	30 Jan 2021 19:42:01
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User entered empty.	System	30 Jan 2021 19:48:16
User entered '13 Oct 2020 12:00'	System	30 Jan 2021 19:42:16
User entered '13 Oct 2021 12:00'	System	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'I'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User entered '0'	System	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04
User entered 'I'	System	30 Jan 2021 19:42:01

US3172349

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:37:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:04

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:37:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:38:16
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:36:18

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: MILI [ETHINYLESTRADIOL;NORGESTIMATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 12:41:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 12:41:47
Data point term sent to Coder	System	03 Sep 2020 19:37:50
User entered 'MILI'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'CONTRACEPTION'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '0.250 / 0.035'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'UN Aug 2019'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	30 Sep 2020 22:26:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '22 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	30 Sep 2020 22:26:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User entered '1'	System	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User entered '1'	System	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:49:12
User entered '804 (804)'	System	03 Sep 2020 19:37:33

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 23:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 23:37:46
Data point term sent to Coder	System	10 Sep 2020 23:36:43
User entered 'acetaminophen'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'back pain'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '500'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'once (ONCE)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered empty.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '09 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '0'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered '09 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:25
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User entered empty.	System	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User entered empty.	System	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:27:30
User entered empty.	System	10 Sep 2020 23:36:16

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: ESTARYLLA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 04:08:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 04:08:00
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 22:03:33
User entered 'estarylla (norgesestimate 0.25mg/ethinyl estradiol 0.035mg)'	Mariete Rendon (b) (4)	18 Nov 2020 22:02:50
	(b) (4)	

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:58:35
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	16 Dec 2020 14:18:02
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Dec 2020 14:17:11
	(b) (4)	
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:39:52
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Nov 2020 22:02:50
	(b) (4)	

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'contraception'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0.25/0.035'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '15 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 22:02:50

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:37:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:42:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:41:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:19:17
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 14:02:25

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:17

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '06 Oct 2020'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:20:02

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:17

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'REST OBSERVATION'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:20:02

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:20:02

US3172349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:17

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 19:20:02

US3172349

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:37:17

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:24:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered '23 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:02:19

US3172349

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:37:17

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:24:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'Pregnancy (PREGNANCY)'	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:02:19

US3172349

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:37:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:24:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 14:02:19

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'USA-US118-2020-MRNA-1273-P301000005'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '22/Oct/2020 13:41'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:17

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.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '29/Oct/2020 16:36'	System	29 Oct 2020 16:36:51

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:17

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.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:08:46
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 16:36:51

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '20/Jan/2021 09:08'	System	20 Jan 2021 14:08:43

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:17

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.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:08:46
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 14:08:43

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:37:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '20/Jan/2021 11:23'	System	20 Jan 2021 16:23:08

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:37:17

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.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 16:23:12
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 16:23:08

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:37:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '16/Feb/2021 20:43'	System	17 Feb 2021 01:43:13

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:37:17

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.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 01:43:13

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:34:02
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:37:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:32:50
	(b) (4)	
User entered '23/Mar/2021 10:05'	System	23 Mar 2021 14:05:34

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:37:17

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.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:32:50
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 14:05:34

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered	System	22 Oct 2020 13:40:56
'USA-US118-2020-MRNA-1273-P301000005'		

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'No (N)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Yes (Y)'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Mark'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'Kutner'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:41:19
User entered 'FL'	System	22 Oct 2020 13:40:56

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:36:43
User entered 'US'	System	22 Oct 2020 13:41:28

US3172349

Folder: SAE USA-US118-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Mar 2021 14:05:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:34:02
	(b) (4)	
User entered '5'	System	17 Feb 2021 01:43:13
User entered '4'	System	20 Jan 2021 16:23:08
User entered '3'	System	20 Jan 2021 14:08:43
User entered '2'	System	29 Oct 2020 16:36:51
User entered '1'	System	22 Oct 2020 13:41:28